Food Drug Cosmetic Law

The Addition of Chemicals to Foods . . . . . .

Application of the Federal Act to New Drugs . . . .

Import Control under Federal Laws . . . . . .

The Formulation of Mandatory Food Standards . . .

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The FOOD DRUG COSMETIC LAW QUARTERLY is an original publication in the field of this law, which has a great and lasting value to all interested in its subject. For the QUARTERLY is designed to provide a constructive discussion of this law, through authoritative papers on it, in order to accomplish significant objectives. They are: (1) to create a better understanding of the law; (2) to further a due solution of its problems; (3) to achieve a high state of its operation, application and development; and (4) thus to secure a maximum attainment of its great remedial purposes, which are to safeguard the health of our people and to protect them from injurious trade deceit. In short, while this law receives appropriate consideration by the officers who administer it and the courts which enforce it, there remains the need for its basic study as a fundamental law of the land and for the objectives stated. And the QUARTERLY is intended to satisfy that need.

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FOOD DRUG COSMETIC LAW QUARTERLY

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The Addition of Chemicals to Foods

W. B. White, Ph. D.

EVEN HE WHO RUNS MAY READ, rather frequently, in the daily press, and even more frequently in the food trade press, about some brand-new chemical which has been proposed for direct or indirect incorporation into our daily food supply. Of course the term "chemical" is a broad one, and it thus seems well to define it more closely for the purposes of this discussion. I shall not include within its scope that relatively large group of chemicals which are prepared directly from plant or animal materials, many of which have themselves been eaten as food by man at some stage of his lengthy career, with no untoward physiological effects. Accordingly such materials as natural pigments, colloids, glucosides, extracts, and other "isolates" are not dealt with. We are, rather, concerned with those increasingly numerous chemicals whose relationship with tried and true foods is so distant that we can only remotely guess as to their effect—good, bad or indifferent—on the human animal. It is a trite, but sound, proverb, that the proof, in fact the *only* proof, of the pudding is in the eating.

Nitrogen Trichloride for Bleaching Flour

There were a great many of these chemicals being added to foods in the early days before Food and Drugs Act No. I, and the battles waged by Dr. Wiley against sulfur dioxide, benzoates, flour bleaches and coal-tar dyes are indeed "old, unhappy, far-off things and battles long ago." I might add that, in one case at least, the unhappiness may prove a continuing one. By way of illustrating what is really the text of this discourse ("you can't be really sure the chemical is innocuous even after long experience"), let me start with the recent rather startling chapter in the story of bleached flour. The nitrogen trichloride bleaching and "matur-

ing" process has been in use for some 30 years, and in all this time no ill effects have been noted on consumers of bread and other white flour products. Then, out of a clear, or only slightly clouded, sky came a recent English scientific paper citing strong evidence that flour thus "aged" produces running fits in dogs! The owners of the process, and other workers, including members of the Food and Drug Administration, have abundantly confirmed the initial work. Cats, rabbits and ferrets are affected, but no other experimental animals thus far tested. The difficult matter of testing the flour on human beings is under intensive investigation, and in the meanwhile the flour and baking industries are frantically seeking satisfactory substitutes for nitrogen trichloride.

By way of driving home the general thesis of this paper, several other episodes will be cited, some recent, others more remote, where actual illness, serious crippling, and even death, have followed closely on the heels of a disastrous guess by some responsible person in the food industry. There was no background of experience in any of these cases. It just "seemed like a good idea at the time" to put these chemicals into a food or a drink. In some cases, even a cursory search of the literature on the toxicity of the chemical would have warned the user to stop, look, and listen before he let the genie out of the bottle.

Monochloroacetic Acid in Beverages

In the first, and most recent, instance, a public trade notice had already issued from the Food and Drug Administration warning that

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Chief, Food Division
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monochloroacetic acid was regarded as an injurious chemical preservative. Notwithstanding this, a manufacturer of a near-orange drink had apparently been sold a bill of goods on the efficacy of this preservative, and perhaps on its innocuous nature and the difficulty of detecting it chemically as well. The consumption of the preserved beverage resulted in an extensive, and fortunately highly localized, outbreak of vomiting and diarrhea. But the lesson did not spread, and later the wine industry lost scores of thousands of gallons of wine by seizure, though fortunately no illness was noted from its consumption. Such occurrences, and the more serious ones cited below, indicate the wisdom of Congress in declaring (in Section 402(a)(2) of the Food, Drug, and Cosmetic Act) a food to be adulterated "if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406." The latter section opens thus: "Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402(a)."

Ortho-Cresyl Phosphate in Beverages

Another episode goes back to the "roaring twenties" when the alcoholically arid Middle West was badly in need of some "Kind Nepenthe." An obliging manufacturer of what he euphemistically labeled "Liquid Medicine" supplied their need by the barrel. It looked like fluid extract of Jamaica ginger, but unfortunately it was so mild in flavor as to be drinkable. It was playfully known as "ginger Jake," and on superficial chemical analysis it behaved like fluid extract of Jamaica ginger. This behavior was due to some ortho-cresyl phosphate which a bright young chemist advised the manufacturer would do the trick. But it did another trick, and a horrible one. By an almost (but not totally) unforeseeable physiological action it permanently paralyzed hundreds of its victims from the hips down. The liquid medicine was indeed very bad medicine.

Diethylene Glycol Solvent for Sulfanilamid

The next story deals primarily with drugs, but the sequel has a food angle which fortunately was not tragic. It is cited mainly to illustrate what may be called a corollary to our main thesis: that the food industry would at times profit from a sidelong glance at experiences in the field

of drug therapy which might throw light, and a red light at that, on what may be anticipated, or feared, by the dosage of food with a given chemical. Like the ginger Jake story, it is perhaps a twice-told tale, but it seems helpful to place these episodes side by side, for what I believe the Law calls their cumulative effect. Once again a young chemist "guessed" that diethylene glycol would be an ideal solvent for sulfanilamid, which is nearly insoluble in water. It was, but the "elixir," sold over the counter and prescribed by physicians, killed some 107 hapless sufferers from diseases that might have been successfully treated with sulfanilamid itself. In the meanwhile, this same solvent, diethylene glycol, had been found "ideal" for household extracts. Not only did it save alcohol and glycerine, but it was said to keep the flavors from "freezing out" of ice cream or "baking out" of cake. Fortunately these extracts had killed no one, or at any rate no deaths had been traced to them, which is by no means the same thing. It goes without saying that there was a prompt round-up of these potential killers by state and federal officials. The Food and Drug Administration managed to get hold of 103 shipments of the solvent and 104 shipments of extracts containing it, but again the lesson had been learned the hard way. Incidentally, some work by the Food and Drug Administration's Division of Pharmacology on the chronic toxicity of ethylene glycol, and its ally, diethylene glycol, neatly illustrates a point made later in this discussion, namely: that animal experimentation should be continued *for the full life span* of at least one of the species employed. It takes about two full years (and a rat is senile at that age) for the characteristic lesions, kidney and bladder stones, bladder tumors, etc., to manifest themselves.

Cyanide Fumigation of Dried Fruits

Another episode occurred in 1936, and it so happened that I was the recipient of the consumer complaint. An unusually intelligent consumer came into the office with a half carton of raisins, and the story that she and two other members of her family had eaten a handful between meals, and soon after, all had experienced violent headaches. Thinking nothing of it, they had eaten some more the next day. The headaches recurred, however, and one of them saw a doctor. He reported "tachycardia," which seems worth five dollars all by itself. That was the whole story—nobody dead or even seriously ill; and it looked like a false scent if there ever was one. However, we went to our chief medical

officer, who happened to have the keenest nose for HCN of any one in the organization. A dozen or more of our scientific staff could smell nothing, but since this physician's "hunch" tallied with the vague symptoms, we had one of the chemists make an analysis for this deadly chemical. He reported 3000 parts per million—a whole 3/10 of one per cent. An unopened package, from the same store and bearing the same code mark, showed 2700 parts; another chase was on. Over a quarter of a million pounds were seized and subsequently destroyed (since all efforts to de-gas the raisins were unavailing). There had, of course, been numerous studies of cyanide retention by various foods subjected to the then popular cyanide fumigation process for dried fruits. These fruits showed no serious retention, and there seemed little cause for concern, though it did seem to be going a little too far when a prominent health official asserted, in a public address, that the fact that no deaths had been traced to the eating of cyanide-fumigated foods proved that this fumigation process was safe from a consumer standpoint. *But*, these particular raisins had been fumigated on the dock (there was a strike on) by covering with a tarpaulin, and squirting the liquid fumigant right against the nearest shipping cartons, through a hose. Under such emergency conditions, the old dogmas simply did not hold. As for the other dogma, that no deaths prove safety, that, too, went by the board when I said to our medical officer, "It's lucky that someone was not killed by those raisins"; and he replied, with profane emphasis: "How do we know that? There are few physicians who would diagnose such poisoning correctly." Then there is the minor dogma, that there are no symptoms of cyanide poisoning, other than death. There *were* other symptoms in this case. Voltaire said, "As I become older, I put away my certainties." Perhaps we had better be as cautious as the Vermont Yank who said, in reply to the remark, "There's a white cow over on that side hill," "Well she's white on this side."

Thiourea Treatment of Fruit

Two more modern incidents will be cited, the second of which began to break while this paper was in preparation. The first has to do with that literally magic chemical thiourea. It serves, like that flour-bleaching story, to illustrate forcibly that one can never be sure a chemical is "harmless" even with a very considerable pharmacological background. It also shows the wisdom of taking into account any collateral information

in the field of drug therapy which, even by analogy, may throw light on the vexing question "*How* safe is the chemical?" But, to return to the amazing properties of thiourea:· Traces of it prevent the cut surfaces of fruit from darkening on exposure to the air. Such traces also slow down corrosion and prevent loss of color in canned fruits; and again they decrease enormously the storage decay of citrus fruits. Inquirers were cautioned that a survey of the literature gave no assurance that such food uses were entirely free from danger, and, in the meanwhile, the Food and Drug Administration started some studies on the effect of thiourea on experimental animals, and also on the closely allied question of methods for thiourea determination in citrus juice. There had already been considerable experimentation with citrus, and this chemical seemed to furnish the pat answer, since it enormously reduced losses from the ravages of rot, blue mold, etc. *But* it was also said to penetrate deeply into the flesh of the fruit, and this we soon confirmed. A few years before, we had been able to persuade manufacturers against using thiourea as a dip for cut fruit, but here was a case where the chemical was not only *on* but *in* the fruit, and a fruit, at that, whose juice was highly prized as a source of ascorbic acid in the diet of infants and children. Animal experimentation had thus far disclosed some moderately harmful effects on rats where the chemical was fed in fairly large amounts, but nothing had developed which promised to look very alarming to a commendably skeptical court or jury. But it so happened that, at about this time, a close ally of thiourea, called thiouracil, had been given extensive clinical trials as a treatment for hyperthyroidism. Quite unexpectedly, out of several thousand patients, a small percentage had developed an exceedingly bad blood picture, and a goodly portion of this small group had been killed outright. One of the unexpected features seems to be the utterly capricious relationship between dosage level and extent of injury. Accordingly, our Division of Pharmacology undertook some further work on rats with special reference to the blood picture. We happened at this time to have some thiourea-treated oranges which showed about 45 ppm of thiourea in their juice, and this juice was fed to a group of six adult rats, with the totally unforeseen result that two of them died a few hours after a single feeding of the juice. They were found upon post mortem to have extensive pleural effusions, and this was also true in less degree on the four survivors. Similar experiments have since been made, and similar results obtained, on large groups of rats.

Feeding rats straight thiourea solution, or the juice of untreated oranges with thiourea added to it, gave identical results for the same dosage, so there is not the slightest question about the facts. But it is not quite correct to call these results "totally unforeseen." As is often the case, there were scattered findings in the literature, not confirmed by other workers, which foreshadowed such a result. As someone has said, "Foresight is at its very best when looking backward."

Benzene Hexachloride as Soil Chemical and Vegetable Spray

The final story is that of a potato grower, harassed by the problem of wire worms in his crop. He was advised to try, experimentally, the incorporation into the soil of one of the magic new organic insecticides, called by various trade names but now christened benzene hexachloride by disinterested scientists. The chemical is volatile, and the hope was that it would kill the worms in the fall, and evaporate by spring. Perhaps it did, but in the spring a young Sunday Supplement reporter's fancy lightly turned to thoughts of a good "story." He came out with a splurge on this patent worm killer, and many of the growers seem to have gone all out, even putting the chemical in the soil after the plants were well up! Again the totally (or should we say *almost* totally?) unexpected happened. The potatoes, when harvested, were so tainted with the chemical that consumers couldn't eat them. It is hopeless to attempt to put a taste or smell into words, but "musty" was the most common term consumers gave the admittedly evil flavor. At any rate, it seemed to stay in the mouth for hours, and it has long been known that the odor of the commercial insecticide is most persistent, far-reaching and unpleasant. The potatoes were scattered up and down the Atlantic seaboard before the facts were known, so subtle is the onset of the very non-rose-like scent. Since the exploitation of this insecticide has far outrun any full knowledge of its toxicity, of its composition, and of methods for its determination in foods, the problem presented to regulatory officials, raw products graders, distributors, and exporters is better imagined than described. At the time this went to press, there were at least four states with potato trouble, with rumors of two others. There were also reports that experimental peas and lima beans were similarly affected. Experimental work with potatoes indicates that benzene hexachloride, whether sprayed on the tops or worked into the soil, brings about very deep-seated changes in the plant—yield and appearance are greatly en-

hanced, red-skinned varieties come out white and potatoes without netted skins come out netted. One is reminded of the old fable of Pandora's box! We have not been able to find any of the chemical in the tainted potatoes, nor does the flavor seem to be due to solanine or other toxic alkaloids. There has thus far been no evidence of illness, but the evil taste itself seems to cause vomiting in a few sensitive persons.

Responsibility of Chemical Manufacturers

Naturally the various regulatory agencies have a very real obligation placed upon them by the statutes and ordinances which they enforce. But is it not about time that the manufacturers of chemicals shouldered more of the responsibility than some of them have yet done? Many, probably the great majority, have; but there are some who take the attitude a sales manager expressed in an interview a few years ago: "We figured that the annual production of (naming a staple food) was 15 billion pounds, and if we could get 0.1 per cent (naming a chemical preservative) into all of it we would sell a helluva lot." Such an attitude reminds one of what the engineer on a railroad in Northern California told Kipling in the late eighties: "We guess that a trestle will stand forever, and we guess we can patch a washout on the track, and we guess the road's clear; and sometimes we guess ourselves into the *deepo*, and sometimes we guess ourselves into Hell." Among the questions which we feel should not be left open until the proverbial chemical horse gets out of the chemical manufacturers' stable and into the American food supply, are these:

Do the pharmacological literature and the medical literature throw any light at all on the prime question, is the chemical a poisonous or deleterious substance in and of itself?

What further work is called for in order to settle that very difficult question?

What chemical methods are ready-made for accurately determining the chemical in the foods in which it is proposed to incorporate it; and if there are none (as is frequently the case) what should be done about it and just who should do it?

A corollary question is: Will these methods, when developed, be applicable to the tissues and body fluids of the experimental animals on which the toxicity is to be tested?

Just what is the crying need for incorporating the chemical in foods, especially if it turns out to be a poisonous substance, contrary to the first "guess"?

Questions in Promulgation of Food Standards

There are certain other questions which are minor as far as the main theme of this paper is concerned, which is, of course, public health. But they may turn out to be major questions "in the interest of fair dealing with consumers," and this is the mandate Congress has placed on the Federal Security Administrator whenever he promulgates any sort of food standard (Section 401 of the Act, opening sentence).

Some of these questions are:

Does the chemical so change any of the characteristics of the food as to conceal damage or inferiority, to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is?

Is it a chemical preservative subject to label declaration as such?

If so, can, and will, it be used as a substitute for good food-factory housekeeping and sanitation?

Study of Chemical for Toxicity

The Administration's Division of Pharmacology has proposed a program for chemical manufacturers, and the food industry they seek to serve, to obtain at least the first approximation to an answer to the broad question, "Is the chemical a poisonous or deleterious substance?" This paper, by Dr. Woodard and the late Dr. Calvery, was published in the January 1943 number of *"Industrial Medicine,"* and it deserves careful reading.

The "general plan of procedure" there given for the study of a chemical for toxicity looks difficult, and it is; the fact that we cannot, except by some chance (or is it mischance?), evaluate precisely the toxicity of "food chemicals" to humans is the great stumbling block in the drawing of dogmatic conclusions from animal experimentation. And when some venturesome soul eats a gram or so of some chemical and announces that he feels fine, about all one can conclude is that he is venturesome and that the chemical is unlikely to kill consumers outright.

or at any rate not right away. If we could control his intake for years, and then kill him and perform a careful autopsy, perhaps some real information might be obtained. But such proceedings are unpopular under our form of government, and so the best rule is to take very seriously any damage done to the experimental animals, and to view with little or no complacency the failure to cause such damage.

The proposed outline may be paraphrased thus:

First, study the effects of the potential poison upon such things as blood pressure, respiration, heart rate, nerve reflexes, muscle motility on organs perfused with the chemical, and on isolated tissue preparations suspended in it. Such preliminary studies will often give direction to further studies.

Next, study acute toxicity on three or more suitable species of animals, administering the substance orally, and also by injection into the skin, the circulation, and the peritoneal cavity. By graduating the dosage up to the point where half the animals are killed (this dose is called, "L D 50") the steepness of the "dosage response curve" can be learned, and visible damage to organs and tissues can be pretty well assured. Conduct the subacute studies by determining the effect of rather large doses (oral or injected, as seems suitable) on the growth of 21-day-old rats for at least 12 weeks, so as to include their period of maximum growth. The symptoms, microscopic pathology, etc., will give valuable information on how to conduct the chronic studies later.

Conduct the chronic studies on at least three species of animals, one of which species is fed during its entire normal life span (2 years for the rat). Graduate the dosage levels so as to bracket the two extremes: no visible injury, and definite lesions with possibly a shortening of the life span. Study effect on reproduction, on the blood picture, etc.; also study the absorption, excretion, and (upon autopsy), the distribution and storage of the chemical.

A few valuable hints are given on the interpretation of the data derived from these studies. There are few methods of analysis where careful consideration of the many variables (avoidable and otherwise) will yield larger dividends than in toxicological bio-assay. The unavoidable variables must (or should) be cancelled out by a statistically planned experiment. It will suffice to say here that the following factors may at times exert an important influence on results within the same species:

sex, age, weight, environment, amount of physical exertion, stage of pregnancy or lactation, whether the substance is administered with food or between meals, the type of diet (protein or calcium level, e. g.), the state of nutrition, and whether or not the individual animal has an infectious disease or suffers from renal, cardiac, or hepatic insufficiency.

The variations between species may be dismissed with a direct quotation:

"Direct translation from lower animals to man in terms of milligrams per kilogram of body weight is rarely possible and sometimes ludicrous. For example, the rat can tolerate 100 milligrams of lead per kilogram per day, for at least a year, and survive, which in terms of a 70-kilogram man would mean 7000 milligrams per day. This is, in the minds of some investigators at least 5000 times the amount that could be tolerated . . . Moreover, it may not occur to many that man is more susceptible to the majority of toxic substances than any other species . . . In applying animal toxicity then, we must allow for a probable flattening of the dosage response curve for man, because of the fact that experimental animal colonies show less variability in their response to poisons."

The paper closes on a note of caution which is well worth quoting, and remembering too, when one is conferring with some particularly pleasant chemical manufacturer:

"In studying a toxic agent, one is likely to be considering only his own particular problem. However, he should not forget that the public is exposed to other poisons every day. There is the possibility that some of these poisons may have an additive or summation effect. Therefore, it becomes necessary to consider all possible sources of poisoning at the same time, in order to come to a judicious conclusion."

Purposes Behind Addition of Chemicals

It is not the province of this paper to name all the chemicals that have been added to foods, or are being more or less actively advocated for that purpose. Some idea of the rather wide variety of the reasons for such addition already will have been gained from the various poisoning episodes cited earlier in this paper. The purposes behind the addition of these seven chemicals were, in order, to do in a hurry to the baking properties of flour what it takes a long time for nature to do; to do away with, or cut down the temperature of, pasteurization; to so adulterate an alcoholic beverage as to make it analyze like fluid extract of Jamaica ginger; to save more expensive alcohol or glycerine; to prevent or eliminate insect contamination; to postpone the onset of decay in oranges; and to kill wireworms in potato fields.

Proposed chemicals multiply almost daily, and they seem to cross-fertilize in amazing fashion. In other words, the situation in food technology seems to be tending in the same direction, and with the same accelerated tempo, as in the field of synthetic drug therapy, where we have the synthetic organic chemist, the pharmacologist, and the practicing physician collaborating closely in the stamping out of disease. But there is this difference between foods and drugs: the latter are, in most cases, admittedly poisonous substances administered to afflicted patients under such close supervision that the beneficial effects promise to outweigh the toxic ones. But foods are consumed by all, and the beneficial effects of the chemical go only to such features as improved appearance, texture, "body," keeping quality, suitability to streamlined production, resistance to attack by plant disease, insects and other vermin; cheaper production and handling costs; enhanced flavor; greater uniformity; cutting down acidity or alkalinity; "saving" expensive ingredients; and keeping moisture (or air) in or out, as desired.

Other Potentially Toxic Chemicals

Only a few of the numerous classes of added chemicals call for extended comment on their potential toxicity. Among those which may be dismissed with bare mention are the coal-tar dyes; most of the bleaches (some are also preservatives); the drying, or "free-flowing," agents; the gases (to displace air, or to increase volume); the relatively non-toxic metals and their salts; the changers, or "holders," of acidity or alkalinity; and the emulsifiers (there are over 400 of these already, and we seem to be only at the beginning).

Chemical Preservatives

The chemical preservatives deserve a word or two. These, too, multiply almost by the minute. Thirty-eight "anti-oxidants" were listed in 1944 by the United States Bureau of Agricultural and Industrial Chemistry ("A.I.C.-54"), and 35 of the quaternary ammonium compounds were noted more than a year ago in the technical and patent literature. Some of the latter are also deodorants, and some of them are so advertised that there is more than a hint to "leave a kiss within the cup," so as to "sanitize" not only the container but the thing contained.

Insecticides and Fumigants

Another group of chemicals, the insecticides, the fumigants and their close allies, deserve more than passing mention. Some are inorganic, but most of the growing and bewildering host of newcomers are organic chemicals, and very complex and unpredictable ones at that. These, too, seem to burgeon forth at very short intervals. DDT, of course, has become almost a household word. It is perhaps not so well known that its use against certain insect pests, particularly apple pests, seems to have created new problems as well as solving old ones; for some pests, not controlled by it and formerly no great menace, now threaten the very life of the trees themselves. One such pest is the red spider mite, and its threat has brought about a temporary recrudescence of an older inorganic insecticide (a selenium compound). The secondary effects of this insecticide have always given responsible agencies much concern. The story of seleniferous soil areas and of "selenophile" vegetation is of course well known. We have evidence that, given the proper soil and climatic set-up, the use of selenium insecticides may actually tend to produce new and man-made seleniferous areas. Another potentially serious secondary effect is that, when farm animals consume seleniferous vegetation and grain, they store it in their flesh and in their eggs. Furthermore, with DDT itself, we have secondary effects which cannot be ignored, since it is known to be stored in the body fat and eggs of farm animals, and to be excreted in the milk of cows and many other mammals including, possibly, the genus homo. Meanwhile, we have in the offing the treatment of plant diseases, and the attack on insect pests too, by adding the chemical to the soil for the plant to absorb through the medium of its root system; one might compare this to the use of drugs in human medicine. The possible far-reaching evil effects of this practice on both agriculture and on the consumer need no elaboration. The potato incident, already related, is a case in point. And, speaking of potatoes, we have a chemical plant hormone ("auxin" is the scientific term) being pushed as a depressor of the well-known tendency of potatoes to sprout in storage. The United States Department of Agriculture recently put out a press notice warning that this, too, may injure the flavor of the European staff of life. As if this were not enough, the weed-killing chemical "2-4 D" has been exploited as a "chemical frost" to kill the potato tops before digging. What this will do to the flavor, and to the metabolism of the much-drugged potato, nobody yet seems to know.

Symptomatic of a still newer trend is the proposed addition of a mixture of pyrethrins and piperonyl butoxide to the paraffin used to coat cheeses during the ripening process. Both together kill the cheese mite better than either alone; in fact, pyrethrins alone don't seem ever to worry him. This geometrically progressive effect (the jargon word is synergism) is evident elsewhere in the fields of animal toxicology and truck crop entomology. Rotenone and piperonyl are said to act synergistically on the bean beetle, and certain pairs of the benzene hexachloride isomers seem to synergize the acute toxicity to experimental animals. In such a welter of complexity, who can say what new and untried chemical is "safe" in food when it is keeping steady company with another reasonably tried and true one?

Conclusion

There is a branch of biological science called ecology, whose province is what Omar called "the sorry scheme of things entire." In other words, it is concerned with the interaction and mutual relations between all living organisms (including, of course, man) and their environment. In this age of ever-increasing specialization, and of large-scale food production, manufacturing and marketing, there is developing a rapidly growing need for a broad, "ecological" approach to the subject matter of this paper. Without question, this thought is in the minds of all who serve the public in any capacity whatever, but perhaps there has been too great a tendency in some quarters to place most of the responsibility for the staggering job of translating such thinking into action, upon the shoulders of those nebulous entities which we call "government," "education," and "pure science." As far as the food consumer is concerned, the Food, Drug, and Cosmetic Act places the *legal* responsibility squarely upon the manufacturer or producer of chemically treated food. But, so often, the purely punitive measures provided by that Act come too late to avert the disaster; indeed this must be, from the very nature of things. As far as the addition of an added "necessary" poison is concerned, the decision of the Supreme Court on a similarly worded prohibition in the 1906 Act against all added poisons is as familiar as the Beatitudes:

"It is not required that the article of food containing added poisonous or other added deleterious ingredients must affect the public health, and it is not incumbent on the Government in order to make out a case to establish that fact. . . . The word 'may' is here used in its ordinary and usual signification, there being nothing to show the intention of Congress to affix to it any other meaning. In thus describing the offense

Congress doubtless took into consideration that foods may be used in many ways. Food may be consumed by the strong and the weak, the old and the young, the well and the sick; and it is intended that if any food, because of any added poisonous or other deleterious ingredient, may possibly injure the health of any of these, it shall come within the ban of the statute."

As to the absolute prohibition in the present Act against "unnecessary" added poisons, the courts have sustained seizure actions against beverages preserved with monochloroacetic acid, against beer preserved with fluorides and against salad dressing made with mineral oil. There has as yet been no contest against seizures of a number of foods and beverages preserved with the "quaternaries," nor against seizures of frozen peaches preserved with thiourea. It would seem that the "necessity" for adding poisons needs to be a stern one indeed.

[*The End*]

FOLIC ACID

Folic acid has been demonstrated to be effective in the treatment of macrocytic anemia of sprue and useful in the treatment of pernicious anemia. Folic acid preparations intended for therapeutic use or combinations of folic acid with iron and/or liver should be distributed only for use under professional supervision. In the absence of satisfactory evidence of its nutritional significance, its declaration as a dietary factor in a multivitamin preparation should be qualified by the statement "The need for folic acid in human nutrition has not been established" (Letter of the Commissioner of Food and Drugs).

Application of the Federal Act to New Drugs

THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, containing Section 505, which deals with the requirements to be met before introduction of a new drug into interstate commerce, has been in effect for nearly ten years. When one reflects on the large number of new therapeutic agents, particularly synthetic compounds, which have been developed and marketed during this period of time, it does not appear at all unwarranted to give the new drug section of the Act at least a certain measure of credit for having prevented the occurrence of unfortunate incidents such as the "Elixir of Sulfanilamide" disaster.

It is recognized that the drug manufacturer of any standing is very much concerned with the safety of the products which he markets. Most firms subject their new drugs to an extremely careful process of thorough investigation and system of control. The new-drug applications in these instances often present overwhelming, or at least convincing, evidence that such articles are safe for use. However, not everyone who contemplates the marketing of a new drug is as concerned with the safety of his product as the reputable drug manufacturer. By including Section 505 in the Act, Congress has indicated its intent to protect the public from the hazards attending the distribution of new drugs which have not been adequately investigated to insure safety for use.

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Several articles dealing with explanations and interpretations of the provisions of Section 505 have been written in recent years. Nevertheless, it might be well to reiterate or emphasize certain aspects which have already been covered in these publications and also to elaborate on our present interpretation of some points in question.

Safety and Efficacy of New Drugs To Be Considered

What must be considered in determining whether or not a new-drug application shall be permitted to become effective? The criteria which must be satisfied in this regard are set forth in the provisions of Section 505 of the Act. Van Winkle and the other authors cited in the footnote [1] have indicated in detail the factors which should be considered in evaluating the safety for use of a new drug. However, as will be shown, it is not always an easy matter to determine, on the basis of the evidence available, whether or not a given drug is safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof. Although the primary consideration in reaching a decision as to whether or not an application for a new drug shall be permitted to become effective rests on the question of safety, it also becomes apparent

[1] Van Winkle, Walton, Jr., The Safety of New Drugs, 2 *Stanford Medical Bulletin* 103, August, 1944.

Van Winkle, Walton, Jr., Herwick, Robbert P., Calvery, Herbert O., and Smith, Austin, Laboratory and Clinical Appraisal of New Drugs, 126 *Journal of American Medical Association* 958, December 9, 1944.

Anderson, Carl M., The New Drug Section, 1 *Food Drug Cosmetic Law Quarterly* 71, March, 1946.

Herrick, A. D., *New Drugs*, Revere Publishing Company, New York, 1946.

Smith, Austin, *Medical Research—A Symposium*, J. B. Lippincott Company, Philadelphia, 1946.

Herwick, Robert P., Federal Regulation I—Food and Drug Administration, 8 *Journal of American Pharmaceutical Association* 157, March, 1947.

that the matter of efficacy must necessarily have a bearing on this question. We do not believe that an evaluation of the safety for use of an article is necessarily complete or adequate unless the efficacy of such an article is simultaneously taken into consideration. As Van Winkle has pointed out, it may not be difficult to reach a decision with regard to the safety of a new drug when the evidence indicates that such a drug has little or no toxicity or when the information available shows that such a drug is extremely toxic. The difficulties are encountered when one must consider drugs which have some toxic quality as well as certain therapeutic value. In these instances, the beneficial effects must be weighed against the hazards or potential dangers involved in the use of the product. The efficaciousness of a drug in the treatment of a serious disease condition may easily overbalance the ill effects which such an article is also capable of producing. The converse may likewise obtain. In the latter instance, it would be contrary to the public interest to permit a new-drug application to become effective. Thus, it is evident that efficacy *must* enter into consideration of the safety for use of a new drug.

New Uses for Old Drugs

Is a new-drug application required for an old drug which is to be offered for a new use without alteration in the dosage recognized as safe for the old use of the drug? Under Section 201(p), the regulations state that "newness of a drug may arise by reason (among other reasons) of the newness of such drug in diagnosing, curing, mitigating, treating or preventing a disease, or to affect a structure or function of the body, even though such drug is not a new drug when used in another disease or to affect another structure or function of the body." It has been suggested that this is an unreasonable requirement in that the safety of the article in human use has already been adequately established. But has safety for a new use actually been demonstrated? The safety of the intravenous or intramuscular use of certain mercurial diuretics in the treatment of cardiac edema has been fairly well established. Would the Food and Drug Administration be justified in permitting new-drug applications recommending a similar route of administration and dosage of these drugs for the treatment of a relatively minor condition such as "athlete foot" to become effective? A more subtle factor to take into consideration is the lack of knowledge regard-

ing the response of the body to a drug under various disease conditions. In other words, in what way does disease modify drug action or affect the reaction of the body to a given drug? Para-aminobenzoic acid may have some value in the treatment of typhus fever. Would such a drug necessarily be safe or suitable for a new use in a patient suffering from a streptococcic or staphylococcic infection? The sulfonamides have been demonstrated to be of value, among other conditions, in the treatment of certain severe respiratory infections. However, one must seriously question the safety or suitability of the indiscriminate use of these agents for minor disease conditions or prophylactically against respiratory infections. The widespread development of sulfonamide resistant strains of organisms or of sensitivity to these drugs is certainly not in the public interest.

Habit-Forming Propensity

At present, the development of new synthetic analgesics having narcotic qualities presents aspects in regard to Section 505 which deserve comment. Addiction or habit-forming liability is a very important factor to consider along with the other toxic qualities of a new drug. The evidence in this regard should be complete even though such a drug is intended for use only under a physician's supervision. It is essential that sufficient information concerning the *degree* of addiction or habit-forming propensity of such an article be presented in a new-drug application in order that safety for use may be properly evaluated. For example, would there be justification in permitting an application to become effective for a drug having no therapeutic superiority over morphine but exhibiting an addiction liability comparable to or greater than that of heroin? It would obviously not be in the public interest to do so. On the other hand, assuming that the therapeutic value of a drug clearly outweighs its addiction liability and other toxic effects, would it be sufficient merely to indicate in the labeling that such an article is habit-forming? We are of the opinion that the physician is entitled to know more in this regard and should be given further information, or at least an estimate of the degree of addiction or habit-forming liability involved, in order that he may make safe and wise use of the drug.

Data Required in New-Drug Application

The question as to what kind of evidence and how much data are required in a new-drug application often is asked. A categorical answer

applicable to all new drugs cannot be given, except to point out that the evidence must be adequate to determine safety for use. Van Winkle and others have clearly pointed out that there are wide differences in the toxicity of new drugs as well as varied conditions of dosage, methods of administration, duration of treatment, and seriousness of conditions for which representations are made. It is undesirable, and for that matter foolhardy, even to attempt, except in a general way, to indicate the nature and amount of the studies which would be adequate to establish safety for use. Productive research or investigational work of any meaning cannot be fettered by predetermination. The investigator who is conducting a study on a particular drug should not be given a set of hard and fast "rules" to follow. During the course of investigation of a drug new problems of various kinds often arise and unanticipated side effects or manifestations of toxicity may be noted. The investigator must feel free to modify his scheme of experimentation or protocol accordingly.

Investigational Use by Experts

Section 505(i) of the Act provides that the Administrator shall promulgate regulations for exempting from the operation of the other provisions of this section those drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of drugs. Who are the experts qualified by training and experience to investigate the safety of drugs? Does a practitioner of any of the healing arts dealing with the prescribing of drugs fulfill the requirements? It is obvious that there are varying degrees of expertness insofar as ability to carry out investigational work is concerned, and we do not believe that it is possible to draw a sharp line of demarcation which will serve *in all instances* to distinguish the expert from the non-expert. The manifest toxicity of the drug concerned and the nature of the disease condition in which such a drug is to be employed should supply the answer to this question. A drug which appears to be potentially capable of producing very serious ill effects and which shows some promise of having real therapeutic value in a very serious or ill-defined disease condition should, in the public interest, be investigated, initially at least, only by recognized experts who are without any doubt fully qualified by training and experience in medical research to perform such studies. Although an individual is licensed to practice a healing art and prescribe drugs, he does not necessarily have the training and

experience in investigative work to evaluate the safety of *new* drugs. There are too many opportunities for errors, especially errors of omission, in carrying out studies of this nature.

The question "how many investigators should I send my product to for study in order to satisfy the requirements of Section 505?" is frequently asked. Often it would appear that the Food and Drug Administration gives an indefinite and non-informative reply to this query. Actually no one can give a categorical answer to this question in regard to a new drug, except to indicate, in a general way, the proper approach to satisfying the requirements of submitting adequate evidence of safety for use. A multitude of testimonials from lay users of an article is of little or no worth in evaluating either efficacy or safety. Not infrequently, investigation will also reveal a significant number of dissatisfied users who have, in addition, suffered ill effects or injury from the product. Cursory reports of investigations which do not include at least the bare essentials as to the number of patients included in the study, the diagnoses of the diseases treated, the dosages of the drug and the duration of treatment in individual cases, the clinical and laboratory tests employed, not to mention details of observations on toxic effects or side reactions, obviously are of no great value to the individual who must review a new-drug application and formulate an opinion as to the safety for use of the article. A few well-controlled studies performed by experts of known reputation for high quality investigative work are of far greater value than many inadequately-controlled studies done by individuals who do not have the qualifications or training for such work.

Occasionally a new-drug application for an article which has been studied exclusively in a foreign country is submitted to this Administration. It is not especially difficult to ascertain the qualifications for investigational work of an individual in this country and thereby form an opinion as to the probable value of the study he has performed. However, it is not infrequently difficult or impossible to secure comparable information in regard to foreign investigators. In these instances, the Administration may deem it necessary to demand that some work be done by investigators in this country in order to assure safety for use of the article in question. Although due consideration is given to the foreign studies, it does not appear unreasonable to request, in certain instances at least, the submission of confirmatory evidence by one or more qualified investigators in this country.

Desirability of Standard Dosage Sizes

Occasionally a situation arises wherein several manufacturers submit new-drug applications for the same drug. A problem is presented when different dosage sizes for the same prescription product are contemplated by the various manufacturers. The evidence of safety for use may be fully adequate in all these cases. However, it is not difficult to visualize some confusion arising when such a drug, manufactured or distributed in different dosage sizes by several firms, appears on the market. Many physicians may know the drug only by its common or non-proprietary name. Furthermore, although such practice is subject to criticism, it must be recognized that some physicians are accustomed to prescribing in terms of so many tablets of a drug or of so many cubic centimeters of a preparation in solution. Under the provisions of Section 505 of the Act, it does not appear that the Food and Drug Administration can necessarily require the various manufacturers to agree to "standard" dosage sizes for a particular product. However, it does not seem inappropriate to present this problem to the manufacturers concerned, with the suggestion that some consideration should be given to the advisability of reaching an agreement on the matter of dosage sizes. In the case of a drug for parenteral use, which may be put up in different concentrations and different-sized ampuls by various firms, there may be, we believe, some real cause for concern regarding the possibility of unintentional misuse in some instances. It might be well for both the pharmaceutical industry and the medical profession to give this matter more consideration.

How Long Is a New Drug "New"?

After a new-drug application for an article has been made effective, how long is such an article regarded as a new drug and still subject to continued regulation under Section 505? This is determined largely by the test of experience. A drug which has enjoyed extensive use and evidenced little or no toxic effect would soon lose its "new drug" status. Conversely a drug which has been employed but to a limited extent and which has exhibited serious toxic effects should of necessity remain a "new drug" for a much longer period of time. It would be unreasonable to insist that new-drug applications continue to be submitted for an article which has been generally and extensively used over a period of time

without accompanying ill effects of any significance. Furthermore, it may be unfair to require the manufacturer who holds an effective new-drug application for such a product to continue to comply with the provisions of Section 505 if he contemplates merely a minor change in formula or labeling.

Administration's Review an Added Precautionary Check

The requirements of Section 505 should not be regarded in any sense as an unreasonable demand upon the manufacturer of new drugs. The conscientious individual will recognize that the review of his application by this Administration serves as an added precautionary check on the measures which he has taken to insure the safety for use of his product. In many instances he will welcome criticism of his new-drug application and is grateful when a defect or loophole in the evidence which he has submitted is pointed out to him. He realizes that by not overlooking any deficiencies in his application he may well obviate considerable trouble in the future for himself or the firm with which he is associated and more than compensate for a short period of delay before the drug is marketed. *[The End]*

PHARMACOPOEIAL RELEASE

The Committee of Experts on the Unification of Pharmacopoeias of the World Health Organization of the United Nations, at its recent sessions in Geneva, placed 244 items on its Primary List of medicinal substances. They believe these of sufficient importance for immediate attention and inclusion in a book of "Standards Recommended for Adoption by the Pharmacopoeias of the World." This List will be submitted for review to authoritative medical groups in a number of countries affiliated with the World Health Organization (Release of the Revision Committee of the *United States Pharmacopoeia*).

IMPORT CONTROL

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THE FIRST FEDERAL GOVERNMENT LEGISLATION applicable to foods and drugs regulated those of foreign origin.[1] Federal control of imported drugs preceded its control of those domestically produced by 58 years. During this 58-year period, the Congress passed many import acts of varying scopes. Some of these early acts have been entirely superseded by the Food, Drug, and Cosmetic Act [2] and other acts, but some of them, like the Tea Act,[3] are still in force. Forty-one additional years have passed since the passage in 1906 of the Food and Drugs Act;[4] thus we have had Federal control over imported drugs for a little over 99 years, and over some imported foods for 64 years.

The principal Federal law presently controlling the importation of foods, drugs, and cosmetics into the United States is the Federal Food, Drug, and Cosmetic Act, which is enforced by the Food and Drug Administration, a constituent of the Federal Security Agency. This act includes within its scope many products which are also subject to other Federal acts, such as meats, horse meat, alcoholic beverages, milk, tea, sera, toxins, and fresh vegetables. This overlapping control arises through the broad definitions of foods, drugs, devices, and cosmetics contained in Section 201 (f), (g), (h), and (i) of the Food, Drug, and

[1] District of Columbia local laws excepted.
[2] 52 Stat. 1040, 21 U. S. C. 321 *et seq.*
[3] 29 Stat. 604, 21 U. S. C. c. 2.
[4] 34 Stat. 768 (1906) 21 U. S. C. 1. See 25 Stat. 549 (1888) and 30 Stat. 246 (1898) for early laws applicable to the District of Columbia.

Under Federal Laws . . .

Cosmetic Act, and the special provisions in other acts. However, duplication of effort is kept to a minimum.

The Food and Drug Administration also enforces the Tea Act, the Import Milk Act,[5] the Filled Milk Act,[6] and the Caustic Poison Act,[7] and these acts, with the exception of the Caustic Poison Act, will also be discussed in this paper, as will be the more important of the pioneer acts.

Import Drugs and Medicines Act

Our account begins on June 16, 1848, when Congress passed the Import Drugs and Medicines Act.[8] This act provided for the examination and appraisal of all drugs, medicines and medicinal preparations, including medicinal essential oils and chemical preparations, used wholly or in part as medicine, offered for entry into the United States, and it prohibited the importation of those found to be adulterated or deteriorated. The Act's enforcement was charged to the Secretary of the Treasury, who was given authority to appoint special examiners of such products. This Act is still in force, but is of limited operation.

Tea Act

The Congress on March 3, 1883, enacted the first Tea Act [9] for the purpose of preventing the importation of adulterated and spurious teas. Fourteen years later, on March 2, 1897, it enacted the present Tea Act,[10]

[5] 44 Stat. 1101, 21 U. S. C. 141-149.
[6] 42 Stat. 1486, 49 Stat. 885, 21 U. S. C. 61 (Supp. V, 1939).
[7] 44 Stat. 1406, 15 U. S. C. c. 11.
[8] 9 Stat. L. 237.
[9] 22 Stat. L. 451.
[10] 29 Stat. L. 604.

the new act entirely superseding the old. The Act of 1897 was entitled, "An act to prevent the importation of impure and unwholesome tea." Both acts controlled the quality, purity and labeling of imported teas. The Tea Act prohibits the importation of any tea which is inferior in purity, quality and fitness for consumption to the standards provided by the Act, and all tea offered for entry must comply with all three exactions,[11] and the Act is not concerned with the value of the importation.[12]

The Treasury Department enforced the first act during its entire existence, and the second act until May 31, 1920, when jurisdiction was transferred to the Bureau of Chemistry, of the Department of Agriculture, by an amendment [13] of the Act of 1897. On June 30, 1927, with the reorganization of that Bureau, responsibility for the Act's enforcement was transferred to the Food, Drug, and Insecticide Administration of the same department.[14] Finally enforcement was transferred to the Federal Security Agency when the Food and Drug Administration was taken out of the Department of Agriculture and was incorporated into that Agency on June 30, 1940, by virtue of the President's Reorganization Plan No. IV.[15]

Prior to the passage of the Tea Act, the United States was the unwilling recipient of much low-grade and refuse tea, but now the quality of tea importations has so improved that rejections average only about one-half of one per cent of our total annual importation of approximately one hundred million pounds.

The Tea Act provides for a board of seven tea experts appointed each year by the Federal Security Administrator, and this board fixes uniform standards for consumption for teas to be imported into the United States. The board consists of six members from the tea trade and the Food and Drug Administration's supervising Tea Examiner. It meets every February in the Food and Drug Administration laboratory in New York City, the meeting usually lasting a full week, during which period the members may examine and taste over 500 samples of tea. Samples of these standards are sold at cost to importers to be used as buyers' guides by their agents abroad. Samples are also retained by the Food and Drug Administration as controls. Tea examiners are located

[11] *Butterfield v. Bidwell*, 96 Fed. 328; *Macy v. Loeb*, 205 Fed. 727.
[12] *Carter, Macy & Co. v. Matthews*, 220 App. Div. 679, affirming 247 N. Y. 532.
[13] 41 Stat. L. 712, 21 U. S. C. 41.
[14] In 1930, its name was changed to the Food and Drug Administration, but there was no change of function.
[15] 5 U. S. C. 133 (t) note.

at Boston, New York, San Francisco, and Seattle. These examiners determine the quality and purity of all teas offered for entry into the United States, and those shipments not conforming to the standards set are refused entry by the Customs officials. The Act provides for an appeal to the United States Board of Tea Appeals wherever an importer is of the opinion that the rejection of his shipment of tea is erroneous. The appeal must be filed within 30 days of the rejection.

The United States Board of Tea Appeals, which is made up of three members of the Federal Security Agency, usually operates by calling in three tea experts from the trade, to whom it submits several unidentified samples of similar teas, including a sample of the rejected tea and of the standard. The decision of these experts is accepted by the Board, which makes its decision accordingly. There is no appeal from the decision of this Board. However, the courts will review the findings of the Board when its decision has interfered with a vested right and has been induced by fraud or a mistake of law. The court can and will correct an error of this kind upon suit by the importer. In *Waite v. Macy*,[16] the Supreme Court granted an injunction to the importer requiring the Board to admit a shipment of tea which it had rejected. The regulation calling for rejecting of all tea containing any coloring matter, upon which the rejection had been based, was in conflict with the law itself, and was, therefore, invalid.

In case this Board affirms the rejection of the shipment, it must be removed from the country within six months, and failure to do so will result in its destruction. It may, however, be used for manufacture of chemical products on compliance with the regulations. Once a shipment of tea has been rejected and has been exported from the United States, it may not be reimported, and if reentered it is subject to seizure irrespective of good faith on the part of an innocent importer who had no knowledge of its previous rejection.

The Tea Act also provides for the admission under bond for manufacturing into certain chemical products of tea waste, siftings, sweepings and low grade tea.[17]

The Tea Act did not exclude the operation of the Food and Drugs Act of 1906, nor does it exclude the operation of the Food, Drug, and

[16] 246 U. S. 606 (1918). See also *Buttfield v. Stranahan*, 192 U. S. 470 (1904), and *San Lung v. Jackson*, 85 Fed. 502 (C. C. N. D. Cal. 1898).

[17] Amendment to Tea Act, May 16, 1908, 35 Stat. 163, 2 U. S. C. 41.

Cosmetic Act upon shipments of tea offered for entry, nor upon subsequent interstate shipment of tea, since tea is a food within the meaning of Section 201 (f) of that Act.[18] The label requirements imposed by Section 403 of the Food, Drug, and Cosmetic Act apply to tea in package form. Since tea may become adulterated, or rendered unfit by water or fire damage, or misbranded after entry into the United States, the public needs the protection afforded by the provisions of the Food, Drug, and Cosmetic Act. Interstate shipment of adulterated or misbranded tea is prohibited, as is the case with all foods, drugs, and cosmetics, and such shipments may be seized and the shippers proceeded against in a criminal action or by injunction.

The Tea Act was passed in response to overtures to Congress by the tea industry, which sought to protect itself from the inferior product being forced on it by foreign interests. As noted above, a vast improvement has been accomplished. Since the board of tea experts is made up of members of the tea trade, the control is primarily self-imposed. The cost of enforcement was defrayed by Congressional appropriations until the fiscal year 1940-41, when Congress failed to appropriate any funds for the enforcement of the Federal Tea Act. The tea trade, in order to keep the Act alive, offered to pay the cost of enforcement itself, and its proposal was made by "rider amendment" to the Second Deficiency Bill on June 22, 1940.[19] The cost to the trade amounts to 3½ cents per hundred pounds or fraction thereof.

The tea trade is to be commended for its interest and efforts in keeping the quality of tea imported into the United States so high. The paucity of court actions during the 64 years of the life of the Tea Act is convincing proof of industry backing and cooperation.

Oleomargarine Act

On August 2, 1886, Congress enacted a law[20] which imposed a tax upon and regulated the manufacture, sale, importation, and exporta-

[18] 26 *Opinions Attorney General* 166.

[19] 54 Stat. 632. *Congressional Record*, June 22, 1940. Senate p. 13, 619, House p. 13, 513.

[20] 24 Stat. L. 209. Amended on May 9, 1902, October 1, 1918, July 10, 1930, and February 24, 1933. See also Customs Regulations, Par. 11.5, Part 11, covering import procedure. See also Internal Revenue Regulations No. 9 (26 CFR pt. 310) CR. S. 161, 251, I. R. C. Sec. 2306. 5 U. S. C. 22, 19 U. S. C. 66, 26 U. S. C. 976. See also *McCray v. United States*, 195 U. S. 27, in which the Supreme Court held the Act valid in a case involving the tax power.

tion of oleomargarine, and its enforcement was charged to the Treasury Department.

The tax provisions of the Act and subsequent acts are still enforced by that department, but oleomargarine is also subject to the requirements of the Federal Food, Drug, and Cosmetic Act, as it was to the requirements of the Food and Drugs Act of 1906.

A standard of identity for oleomargarine has been established, as authorized by Section 401 of the Food, Drug, and Cosmetic Act, and imported as well as domestic oleomargarine must conform to the standard.[21] The standard was an extension of the requirement issued under the authority of the Food and Drugs Act of 1906 that vegetable oleomargarine contain a minimum of 80 per cent fat.[22] The standard was upheld by the court in *Land O'Lakes Creameries, Inc. et al. v. McNutt, Federal Security Administrator* (National Co-op. Milk Producers' Federation et al., Interveners),[23] which held that the standardized product was not an imitation butter within the meaning of Section 403 (c) of the Food, Drug, and Cosmetic Act, and further that Section 403 (c) and Section 401 were independent of each other and that oleomargarine was not adulterated because it contained diacetyl, an artificial flavor.

It is beyond the scope of this paper to discuss in detail the rigid requirements of the present Federal Act and the 47 state acts regulating oleomargarine.

Renovated Butter Act

Another Federal statute[24] of limited scope regulates so-called adulterated butter (essentially butter which has been reworked to remove rancidity by use of chemicals) and renovated or process butter which is butter reworked without the use of chemicals. This Act is enforced very much as is the oleomargarine statute, and is enforced by the same department.

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[21] 6 *Federal Register* 2762, June 5, 1941. Standard may also be found in Service Regulatory Announcement, Food Drug Cosmetic No. 2, p. 39, issued July 1944. See also 5 *Federal Register* 4057-4058, October 11, 1940 and 6 *Federal Register* 1990-1992, February 17, 1941, for order and exceptions.

[22] Food and Drug Administration Notice to Packers of Vegetable Oleomargarine, June 8, 1935. Oleomargarine of animal fat origin was subject to same requirement by ruling of Department of Agriculture, issued under authority of the Meat Inspection Act.

[23] 132 Fed. (2d) 653, January 21, 1943.

[24] Act of August 2, 1886 (24 Stat. 840), amended by Renovated Butter Act of May 9, 1902, 32 Stat. 194, 26 U. S. C. 571 (1934), which was amended by Packing Stock and Process Butter Act of June 24, 1946 (Public Law 427).

Import Foods and Drugs Law

The next act dealing with foreign foods and drugs was the Import Foods and Drugs Law, enacted by Congress on August 30, 1890.[25] It provided for "an inspection of meats for exportation, it prohibited the importation of adulterated articles of food or drink and it authorized the President to make proclamation in certain cases." The Department of Agriculture was charged with its enforcement, and the Secretary was authorized to cause inspection of salted pork and bacon intended for exportation to foreign countries requiring such inspection. The Act made it unlawful "to import any adulterated or unwholesome food or drug, or any vinous, spirituous, or malt liquors, adulterated or mixed with any poisonous or noxious chemical, drug, or other ingredient injurious to health." It provided that "whenever the President is satisfied that there is good reason to believe that any importation is being made, or is about to be made, into the United States, from any foreign country of any article used for human food or drink that is adulterated to an extent dangerous to the health or welfare of the people of the United States, or any of them, he may issue his proclamation suspending the importation of such articles from such country for such period of time as he may think necessary to prevent such importation." The Act also made it unlawful to import into the United States any article the importation of which is so suspended. In another provision, the President was empowered to exclude by proclamation certain imports from countries which were unjustly discriminating against American products.

The provision of this Act, conferring authority upon the President of the United States to suspend by proclamation importations of foods and drink adulterated to an extent dangerous to the health and welfare of the people of the United States, apparently was never invoked. Section 11 of the Food and Drugs Act of 1906 [26] contained this language:

"The Secretary of the Treasury shall deliver to the Secretary of Agriculture, upon his request from time to time, samples of foods and drugs which are being imported into the United States or offered for import, giving notice thereof to the owner or consignee, who may appear before the Secretary of Agriculture, and have the right to introduce testimony, and if it appear from the examination of such samples that any article of food or drug offered to be imported into the United States is adulterated

[25] 26 Stat. L. 415.

[26] 34 Stat. 768 (1906), as amended, 37 Stat. 416 (1912), 37 Stat. 732 (1913), 41 Stat. 271 (1919), 46 Stat. 1019 (1930), 48 Stat 1204 (1934), 49 Stat. 871 (1935), 21 U. S. C. 1-15.

or misbranded within the meaning of this act, or is otherwise dangerous to the health of the people of the United States. . . ."

Even though the Act contemplated an actual examination of a sample, followed by the usual hearing accorded to an importer and finding of illegality by the Food and Drug Administration before exclusion of the shipment offered for entry, the section was used by the Food and Drug Administration as a basis for an embargo prohibiting the importation of absinthe,[27] of peyote,[28] and several other products,[29] and of the importation of milk from Canada in 1927 when a typhoid outbreak was raging near Montreal.[30] The Secretary of Agriculture ordered the embargo permanently applied to absinthe, peyote, and other products, but only during the pendency of the outbreak in the case of cream and milk from Canada.

The section of the Act of 1890 quoted above could presumably have been applied in the cases just cited but was not. No court has ever ruled on the validity of any embargo imposed under Section 11 of the Food and Drugs Act.

The Food, Drug, and Cosmetic Act contains no embargo provisions, but the definitions of adulteration, as contained in Section 402 (a) (1), (2), (3), (4), (5), and (6), are sufficiently comprehensive to protect the public against imported foods which may be dangerous to health.

Filled Cheese Act

On June 6, 1896, Congress passed an act[31] "defining cheese and also imposing a tax upon and regulating the manufacture, sale, importation and exportation of filled cheese." The purpose of Congress was to discourage the sale of filled cheese—that is, cheese to which fats, other than butterfat, have been added—and in this purpose Congress has succeeded. Little of the product is manufactured today. The Commissioner of Internal Revenue was charged with its enforcement initially and still enforces the Filled Cheese Act today. Filled cheese, being a

[27] Food and Drug Inspection No. 147, July 25, 1912.

[28] Service Regulatory Announcement, Chemistry No. 13, May 3, 1915.

[29] Service Regulatory Announcement, Chemistry No. 16, 1916, and Service Regulatory Announcement, Chemistry No. 20, 1917.

[30] It is well to note here that a similar situation could now be controlled under the Federal Import Milk Act of 1927 (44 Stat. L. 1101, 21 U. S. C. 141-149), since under Regulation 21 of that Act a permit to ship milk or cream into the United States may be suspended for cause at any time.

[31] 29 Stat. L. 253, U. S. C. 1934 ed., Title 26, Chap. 10. Another similar tax act was the Act of June 13, 1898, taxing mixed flour, amended on February 26, 1926.

food, is subject also to the Federal Food, Drug, and Cosmetic Act, as it was to the predecessor Food and Drugs Act of 1906, but the Federal Food, Drug, and Cosmetic Act did not repeal, modify, affect, or supersede the Filled Cheese Act, since Section 902 (c) of the Food, Drug, and Cosmetic Act specifically so states. Imported filled cheese is subject to all of the provisions of the Act and is, in addition, subject to added duties and taxes.

The regulations are quite strict. All filled cheese must be packed in previously unused wooden cases marked with the words, "Filled Cheese" in large letters, and the cases may not be reused. Retailers may sell only from the original stamped packages and must comply with further marking regulations. Retail and wholesale dealers must prominently display signs reading, "Filled Cheese Sold Here." Additional taxes are imposed on manufacturers, wholesalers, and retailers of filled cheese, and the manufacturers must file all notices, inventories, etc., that the Commissioner of Internal Revenue may require. Penalty for violation of the Act is a misdemeanor and is punishable by fine or by imprisonment.

In the Act of March 1, 1899,[32] there appeared this language:

"The Secretary of Agriculture, whenever he has reason to believe that articles are being imported from foreign countries which are dangerous to the health of the people of the United States, shall make a request upon the Secretary of the Treasury for samples from original packages of such articles for inspection and analysis, and the Secretary of the Treasury is hereby authorized to open such original packages and deliver specimens to the Secretary of Agriculture for the purpose mentioned, giving notice to the owner or consignee of any goods which the Secretary of Agriculture reports to him have been inspected and analyzed and found to be dangerous to health."

Note the similarity of this wording to that of Section 11 of the Food and Drugs Act of 1906 and to that of Section 801 (a) and (b) of the Food, Drug, and Cosmetic Act of 1938.

This Act provided funds for the investigation of adulteration of foods, drugs and liquors, by the Department of Agriculture, and Congress continued such appropriations until the fiscal year 1907.

Virus, Serum and Toxin Acts

On July 1, 1902, Congress passed the Virus, Serum and Toxin Act[33] regulating biological products. This Act was enforced by the

[32] 30 Stat. L. 947, 951.

[33] 32 Stat. 728, 42 U. S. C. 141-148, Public No. 244.

United States Public Health Service of the Treasury Department. The Public Health Service Act of July 1, 1944,[34] is, in reality, a recodification of all of the laws enforced by the United States Public Health Service [35] of the Federal Security Agency, and Section 351 is a reenactment of the Act of 1902.

The new act specifically makes these products subject to the terms of the Federal Food, Drug, and Cosmetic Act enforced by the Food and Drug Administration of the Federal Security Agency, except for the licensing provision contained in Section 505 of the Act of 1902. Congress, while feeling that the controls applied under the old act were quite effective in safeguarding the public in this field, quite properly added the protection afforded by the Federal Food, Drug, and Cosmetic Act, since, under that Act, seizure of a contaminated or dangerous product, which had reached the market despite all safeguards, could be made.

The two branches of the Federal Security Agency involved in the enforcement of these two acts have always avoided a duplication of effort.

However, in the import field, the Virus, Serum and Toxin Act applied only to those products which were intended for resale. Thus, if an importation of one of these products is made solely for use by the consignee, only the Food, Drug, and Cosmetic Act applies to it.

The Animal Virus, Serum, Toxin Law of March 4, 1913,[36] prohibits the importation of viruses, sera, toxins, and analogous products for use in the treatment of domestic animals, unless the importer holds a permit from the Department of Agriculture covering the specific product.

Appropriation Act of March 3, 1903

The Appropriation Act of the Department of Agriculture of March 3, 1903,[37] among other things, provided for the exclusion of articles

"which are forbidden to be sold or restricted in sale in the countries in which they are made or from which they are exported, or which shall be falsely labeled in any respect in regard to the place of manufacture or content of the package."

These provisions next appeared almost verbatim in Section 11 of the Food and Drugs Act of 1906. The first part of this prohibition has

[34] 58 Stat. 682, 42 U. S. C. (Supp. V) 201 *et seq.*

[35] Transferred to the Federal Security Agency by President's Reorganization Plan No. II, 5 U. S. C. 133(t) note.

[36] 37 Stat. 832, 21 U. S. C. 151 *et seq.*

[37] 32 Stat. L. 1147, 1158.

become Section 801 (a) (2), and the second part is embodied in Section 801 (a) (3) of the Food, Drug, and Cosmetic Act.

During the first year of enforcement of the Act of March 3, 1903, all samples were sent to Washington, D. C., for analysis and a determination of the action to be taken. The time required made enforcement impracticable and burdensome, and, in 1904, a laboratory was established at San Francisco and another at the Port of New York. In 1905, additional laboratories were established at Boston, Philadelphia, Chicago, and New Orleans; thus, by 1906, when the Food and Drugs Act was passed, these laboratories were in active operation.

Meat Inspection Act

On June 30, 1906, Congress passed the Federal Meat Inspection Act [38] in response to popular demand, following the expose of the frightful conditions prevailing in the Chicago Stockyards, by Upton Sinclair's significant book, "The Jungle." [39] The day was an important one in the history of Federal food legislation, for Congress also enacted the Food and Drugs Act, making its effective date January 1, 1907. On March 4, 1907, it approved a subsequent Meat Inspection Act.[40] Both Acts were identical at first, but the latter act was amended on July 29, 1938.[41]

The Act applied to cattle, swine, sheep, goats, and meat derived from them, and sought to control these products by inspection and direct supervision *before* shipment in interstate commerce, for the Act is primarily a health protecting measure.[42] The Dairy Export Act of 1908 [43] made the provisions of the Meat Inspection Act applicable to dairy products destined for exportation, and the Act's scope was further enlarged to include horses and horse meat, and horse-meat products, by the Act of July 24, 1919.[44] Finally, the Tariff Act of October 3, 1913,[45] and its successor, The Tariff Act of June 17, 1930,[46] subjected import meat and

[38] 34 Stat. 674.
[39] Published by Scribner's, New York.
[40] 34 Stat. 1260-1265.
[41] 52 Stat. 1235, 21 U. S. C. 71-91.
[42] In this respect, the Meat Act is greatly different from the Food, Drug, and Cosmetic Act, which is invoked against illegal shipments only after interstate movement has already occurred. Also, common carriers are not liable under Section 703 of the Food, Drug, and Cosmetic Act for their participation as carriers in interstate movement of a violative shipment of foods, drugs, or cosmetics, whereas, under the Meat Inspection Act, a carrier moving uninspected meat in interstate commerce is liable to prosecution.
[43] 35 Stat. 251, 254.
[44] 41 Stat. 241 (21 U. S. C. 96).
[45] 38 Stat. L. 114-166, 192-194.
[46] 46 Stat. 689 (19 U. S. C. 1306) (Public No. 361, Seventy-first Congress).

meat products to the control of the Meat Inspection Act. The Meat Inspection Act applies to exportations of meat and meat products, as well as to interstate traffic in them.

The Meat Inspection Act is now enforced by the Meat Inspection Division of the Department of Agriculture.[47] Penalties for its violation can be as high as two years in jail or a fine of $10,000, or both.

In addition to being subject to the Meat Inspection Act, meat and meat products are subject to the provisions of the Food, Drug, and Cosmetic Act (as they were to its predecessor, the Food and Drugs Act of 1906), since they are exempt only to the extent of the application or the extension thereto of the Meat Inspection Act.[48]

Section 403 (i) (2) of the Food, Drug, and Cosmetic Act requires the labels of all foods in package form to bear a list of all ingredients, in terms of their common or usual names, used in the preparation of such food. This provision is not found in the Meat Inspection Act; the labels of canned meat products must therefore bear the declaration of ingredients required by the Food, Drug, and Cosmetic Act. Also there is no seizure provision in the Meat Inspection Act and the seizure provision of the Food, Drug, and Cosmetic Act is sometimes invoked to remove from the market meat or meat foods that have become adulterated subsequent to leaving the inspected establishments.[49]

It goes without saying that jurisdiction over interstate and import shipments of meats from animals other than those listed in the Meat Inspection Act lies only in the Food and Drug Administration. The Food and Drug Administration has seized shipments of rabbits found unfit for food,[50] and would control shipments of bear meat, bison, deer meat, etc., if made in interstate commerce or offered for entry into the United States.

If horse meat from horses which have died otherwise than by slaughter is shipped in interstate commerce, it would be adulterated within the meaning of Section 402 (a) (5) of the Food, Drug, and

[47] See Regulations, United States Department of Agriculture, (a) March 24, 1945 (10 *Federal Register* 3316); (b) September 10, 1945 (10 *Federal Register* 11,638); (c) July 11, 1946 (11 *Federal Register* 7714); (d) September 27, 1946 (11 *Federal Register* 11,189).

[48] Section 902 (b), Federal Food, Drug, and Cosmetic Act.

[49] *United States v. 23 Cases of Canned Cooked Ham*, Food Notices of Judgment 8970 (1945).

[50] Notices of Judgment 20640. *United States v. 4 Barrels of Rabbits* (1932).

Cosmetic Act, and such shipments could be seized by the Food and Drug Administration pursuant to authority granted in Section 304 of said Act.

Import shipments of horse meat have a different status from interstate shipments of horse meat. In the case of import shipments, such entries come squarely under the Food, Drug, and Cosmetic Act, and they are not within the scope of the Meat Inspection Act. If these entries are sound, unadulterated and are not misbranded, they must be admitted. However, subsequent shipment of such an entry in interstate commerce would violate the provisions of the Horse Meat Act of July 24, 1919,[51] since that Act prohibits interstate traffic in horse meat or meat food products derived from horses unless the animals have been slaughtered in establishments under strict Department of Agriculture inspection, and foreign prepared horse meat could not have been prepared originally under such inspection, and such a shipment would subject the shipper to criminal prosecution.

Food and Drugs Act

Chronologically, the next Act which should be presented at this point is the epoch-making Food and Drugs Act, passed on June 30, 1906, by a Congress aroused into action by demands from the public; demands which no longer could be ignored. However, in order to be able to follow the discussion of this Act with an account of the Food, Drug, and Cosmetic Act of 1938, a natural sequence, all other acts involving imported foods, drugs or cosmetics up to 1947 will be treated first, after which we will return to the 1906 Act, concluding this article with an examination of the Food, Drug, and Cosmetic Act of 1938, as it applies to imports.

Narcotic Drugs Laws

Therefore, we next report on the laws governing importation of narcotic drugs. The importation and sale of narcotic drugs fall within the scope of the Narcotic Drugs Import and Export Act of February

[51] 41 Stat. 241 (21 U. S. C. 96). See also Edition of January 1947, Regulations Governing the Meat Inspection of the United States Department of Agriculture, (Code of Federal Regulations, Title 9, Chap. 1, Subchapter A) issued March 24, 1945 (10 *Federal Register* 3316), and including amendments issued September 10, 1945 (10 *Federal Register* 11638), July 11, 1946 (11 *Federal Register* 7714), and September 27, 1946 (11 *Federal Register* 11189).

9, 1909,[52] and the Harrison Narcotic Act of December 17, 1914,[53] as well as being subject now to the requirements of the Food, Drug, and Cosmetic Act.[54] Narcotics have been the subject of much Federal legislation.[55]

Plant Quarantine Act

Importations of many fruits and vegetables fall within the scope of the Plant Quarantine Act of August 20, 1912,[56] as well as being subject to other laws governing the importation of food products. This Act is enforced by the Bureau of Entomology and Plant Quarantine of the Department of Agriculture.

Filled Milk Act

The Filled Milk Act [57] was passed by Congress on March 4, 1923, on the recommendation of the dairy industry.

The Act defines filled milk as any milk, cream, or skimmed milk in any form to which any fat or oil other than milk fat has been added, and declares the product to be an adulterated article of food, injurious to the public health, and its sale a fraud upon the public. The Act exempts distinctive proprietary infant feeding compounds from its provisions but requires special labeling and further restricts their sale. The penalty for a violation of the Act is a fine of not more than $1,000, or imprisonment of not more than one year, or both.

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[52] Act of February 9, 1909 (35 Stat. 614), as amended by the Act of January 17, 1914 (38 Stat. 275), the Act of May 26, 1922 (42 Stat. 596), the Act of June 7, 1924 (43 Stat. 657), the Act of June 14, 1930 (46 Stat. 586)—further amended by Public Law 414, Seventy-eighth Congress, Chapter 377, second session, House of Representatives 4881, classifying a new drug isonipecaine as a narcotic.

[53] 38 Stat. L. 785-790 as amended. Held valid by Supreme Court in *United States v. Doremus* (1919), 253 U. S. 487, No. 853, certiorari denied, in a 5 to 4 decision, in a case involving tax power.

[54] Section 502 (d), Federal Food, Drug, and Cosmetic Act. See also Section 2561, Internal Revenue Code (1939), expressly stating that nothing contained therein shall be construed to impair, alter, amend, or repeal any provision of the Food and Drugs Act of 1906.

[55] See also Act of August 12, 1937 (50 Stat. 627), as amended by Public Law 414, Seventy-eighth Congress. See also the Tariff Act of 1930, 19 U. S. C. 1884, also amended by Public Law 414, Seventy-sixth Congress. See also the Internal Revenue Code, 1939, Chapter 23, Narcotics, also amended by Public Law 414, Seventy-eighth Congress. See also 21 CFR pt. 202.

[56] 37 Stat. 315—amended March 4, 1913; March 4, 1917; May 31, 1920; April 13, 1926; May 1, 1928; July 31, 1947. See Public Law 426, Seventy-seventh Congress, for Act covering importations from Mexico and Agricultural Appropriation Act of May 17, 1935; 49 Stat. 268 for regulations governing sanitary export certification. See also paragraph 12.10, Part 12, Customs regulations, April 13, 1926.

[57] Act of March 4, 1923, 42 Stat. 1486, 21 U. S. C. 61 (1934). Held constitutional by the Supreme Court, *United States v. Carolene Products Co.*, 304 U. S. 144. See also *Carolene Products Co. v. United States*, 323 U. S. 18 (1944).

The Act of 1923 made no provision for assigning the law to any specific department for enforcement, and it was not until August 27, 1935, that its enforcement was charged to the Department of Agriculture by an amendment to the original act.[58] Enforcement was later transferred to the Federal Security Agency in 1940.[59]

The Filled Milk Act, unlike the Federal Food and Drugs Act and Federal Food, Drug, and Cosmetic Act, contains no provision for seizure of interstate shipments made in violation of the law; thus, the government cannot remove products from interstate commerce which it believes to be in violation of the Act. It can proceed only by criminal prosecution and thus obtain judicial interpretation of the Act as it applies to the product made the subject of such action.

Products falling within the scope of the Filled Milk Act, if offered for importation into the United States, would be denied entry.

A study of all litigation involving the Filled Milk Act leads one to the conclusion that further amendment to this Act is needed. Seizure and injunctive remedies should be added as should be a multiple violation clause.

Import Milk Act

Another Act applicable to an imported food product is the Import Milk Act [60] passed by Congress on February 15, 1927, at the behest of United States producers. The Act is applicable only to imported milk and cream. The Act states that its purpose is to promote the dairy industry of the United States and to protect the public health.

The Act prohibits the importation of milk and cream into the United States unless the shipper holds a permit from the Federal Security Administration. Permits cannot be issued unless the producing herd is healthy, and the dairy is sanitary. The Administrator is given power to cause inspections to be made of the producers and he can suspend or revoke any permit whenever he finds that the holder has failed to comply with the Act or its regulations.

The penalty for a violation of the Act is, in addition to all other penalties prescribed by law, a fine of not less than $50, nor more than

[58] Public No. 350, Seventy-fourth Congress, House of Representatives 6361.
[59] President's Reorganization Plan No. IV, June 30, 1940.
[60] 44 Stat. 1101, 21 U. S. C. 141-149.

$2,000, or imprisonment for not more than one year, or both such fine and imprisonment.

Unlike the Federal Food, Drug, and Cosmetic Act, the Import Milk Act applies only to shipments offered for entry into the continental United States, and citizens of Puerto Rico, Hawaiian Islands, etc., are not protected by it.

The Act does not apply to dried, condensed and evaporated milk of foreign origin, nor does it apply to condensed or semi-solid buttermilk imported for animal feeding purposes.[61] (It does, however, apply to sour cream intended for manufacture into butter.) [62] These products, however, are subject to the requirements of the Federal Food, Drug, and Cosmetic Act. At present there are practically no offers of entry of milk and cream, because of changed economic conditions.

Federal Alcohol Administration Act

On August 29, 1935, Congress passed an Act [63] regulating alcoholic beverages and the Act is now enforced by the Treasury Department, jurisdiction having been transferred to it in 1940 with the abolition of the Federal Alcohol Administration. Imported alcoholic beverages are also subject to the requirements of the Food, Drug, and Cosmetic Act of 1938, as they were to the requirements of the Food and Drugs Act of 1906,[64] but the Food and Drug Administration restricts its activity in case of importations of alcoholic beverages to determinations of fitness for consumption and misbranding due to misrepresentation of the product as a drug. The Food and Drug Administration, in enforcing Section 402 (a) (1) of the Food, Drug, and Cosmetic Act, has detained

[61] Trade Correspondence letter No. 77, February 19, 1940.

[62] Notice to Shippers and Importers of Milk and Cream Under the Federal Import Milk Act, March 24, 1928.

[63] Federal Alcohol Administration Act, 49 Stat. 878. See also Act of October 1, 1890, 26 Stat. 621; Act of August 27, 1894, 28 Stat. 568; Act of June 7, 1906, 34 Stat. 215; Act of October 22, 1914, 38 Stat. 747; Act of September 8, 1916, 39 Stat. 785; Act of February 24, 1919, 40 Stat. 1111, for special acts defining sweet wine. See also Act of March 3, 1897, allowing bottling of distilled spirits in bond. See also Liquor Taxing Act of 1934 (amended June 26, 1936, by Liquor Tax Administration Act), Treasury Division 48448, January 11, 1934. Liquor Law Repeal and Enforcement Act, Treasury Division 47862, August 27, 1935. Liquor Enforcement Act of 1926, Treasury Division 48448, June 25, 1936. See also paragraphs 12.37, Part 12, Customs Regulations; 11.6, Part 11; 11.7, Part 11. See also Section 3 (49 Stat. 978); Section 1 (49 Stat. 1152), R. S. 251, 161; 27 U. S. C. 203, 19 U. S. C. 66, 5 U. S. C. 22.

[64] The embargo against absinthe imposed under the Food and Drugs Act of 1906 has been previously discussed. See *United States v. 50 Barrels of Whiskey*, 165 Fed. 966, Notices of Judgment 68 for a case involving seizure of whiskey under Food and Drugs Act.

many import shipments of alcoholic beverages containing glass particles and other contaminants, such as fusel oil, and, in enforcing Section 402 (c), has detained a few shipments because they contained non-certifiable coal tar colors. Actions taken because of false therapeutic claims have been very rare and are not of recent origin. Other violations detected in course of analyses, such as short volume, presence of undeclared certified coal tar colors, etc., are reported to the Treasury Department for appropriate action.

Medicinal whiskey or *Spiritu Frumenti* is considered to be a drug product, within the meaning of Section 201 (g) of the Food, Drug, and Cosmetic Act, and the standard for it may be found in the National Formulary 8th Edition, 1946, p. 555. Whiskey called for in physicians' prescriptions must conform to this standard.

Food and Drugs Act

Dr. Harvey Washington Wiley won the battle he had been waging for 17 years when Congress passed, on June 30, 1906,[65] the Federal Food and Drugs Act. This was the first Federal Act regulating domestically produced foods and drugs. Much has been said and written about this great pioneer in the fight for pure foods and drugs, but a short account of his work is given here for the benefit of those who are not familiar with his story.

Harvey Washington Wiley was born in Indiana in 1844. After his discharge from the Union Army, he studied medicine at the Medical College of Indiana and received the M. D. degree. He then studied the chemistry of foods at Harvard, completing the four-year course in just six months. After this, he became a professor at Purdue. It was here that his interest in food adulteration originated. In 1883, he became Head of the Division of Chemistry of the Department of Agriculture, and in 1901 he became Chief of the Bureau of Chemistry. He exposed the deplorable conditions then prevailing—numerous foods were filthy, poisonous, and disease producing, and many drugs were fakes, incapable of relieving or curing the diseases for which they were recommended, or they were actually harmful, containing habit-forming drugs. Dr. Wiley did more than just expose and condemn. He showed manufacturers

[65] Held constitutional — ***United States v. Sweet Valley Wine Co.***, 208 Fed. 85. ***McDermott et al. v. Wisconsin***, 228 U. S. 115.

how to put up pure foods, and many of them became his converts. His fight was long and disheartening. He saw food and drug bills killed in committee 17 years in succession. During the struggle, Dr. Wiley continually made friends. The Women's Clubs of America joined his crusade and their members deluged all of the members of the Congress of 1905 with telegrams urging the passage of a food and drugs act. Congress heeded the public demand. At last, Dr. Wiley had won his battle!

The Act was subsequently amended as follows:

(1) In 1912 by the Sherley Amendment.[66] The amendment was made necessary by the ruling of the Supreme Court in *United States v. Johnson,*[67] holding that the misbranding section of the Act did not cover therapeutic claims.

(2) In 1913 by the Gould Amendments.[68] This amendment required the declaration of net contents on the labels of all food in package form. The amendment was held constitutional by the Supreme Court in 1932, in *United States v. Shreveport Grain and Elevator Co.*[69]

(3) In 1919 by the Kenyon Amendment.[70] The purpose of this amendment was to clarify the phrase "in package form" as used in the Gould amendment, and it brought wrapped meats within the definition of food in package form. This amendment was not repealed by enactment of the Food, Drug, and Cosmetic Act.[71]

(4) In 1923 by the Butter Standard Amendment,[72] which set the minimum fat content of butter at 80 per cent. This amendment was not repealed by enactment of the Food, Drug, and Cosmetic Act.[71]

(5) In 1930 by the McNary Mapes Amendment,[73] which made it possible for the Food and Drug Administration to set up food standards having the force of law. Standard-making authority is now found in Section 401 of the Food, Drug, and Cosmetic Act.[74]

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[66] 34 Stat. 416, 21 U. S. C. 10—held constitutional in *Seven Cases of Eckman's Alterative v. United States*, 239 U. S. 510, also in *United States v. American Laboratories*, 222 Fed. 104.

[67] 211 U. S. 488 (1911).

[68] 37 Stat. 732 (1913), 21 U. S. C. 10.

[69] 46 F. 2d 354, reversed, 287 U. S. 77 (1932).

[70] U. S. C., 1934 ed., Title 21, Section 10, 41 Stat. 271 (1919), Ch. 26.

[71] Section 902 (a), Federal Food, Drug, and Cosmetic Act of 1938.

[72] U. S. C., 1934 ed., Title 21, Section 6, 42 Stat. 1500, Ch. 268.

[73] 46 Stat. 1019 (1930), 21 U. S. C. 10.

[74] Section 401 of the Food, Drug, and Cosmetic Act prohibits the setting up by the Administration of a definition and standard of identity and standard of quality for fresh or dried fruits, fresh or dried vegetables or butter, except for avocadoes, cantaloupes, citrus fruits and melons, but further requires that any definition and standard prescribed for the last four named products relate only to maturity and to the effects of freezing.

(6) In 1934 by the Sea-Food Inspection Amendment,[75] which provided for continuous inspection of sea-food packing plants by inspectors of the Food and Drug Administration. The Amendment remains in force [76] under the present act.

Each of these amendments, except the Sea-Food Amendment, applied to imported products as well as to domestic products.

The law became almost universally known as the Pure Food Law. The Act was:

"for preventing the manufacture, sale or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines and liquors, and for regulating traffic therein, and for other purposes."

Discussion of the import procedure under the 1906 Act will be combined with a discussion of Section 801 of the Food, Drug, and Cosmetic Act and the regulations thereunder.

This Act became the most important act regulating foods and drugs, including those of foreign origin, until supplanted in 1938 by the more modern and stronger Food, Drug, and Cosmetic Act. The new act contains many provisions of the old. In fact, no extensive changes were made in the Import Section of the Food and Drugs Act, and it was incorporated almost bodily into the new act, since it was felt by all concerned that it was adequate and that it worked well. However, the embargo procedure applied under the 1906 Act (previously discussed) has not yet been used under the new act.

The last proviso of Section 11 of the Food and Drugs Act of 1906 became Section 801 (c) of the Food, Drug, and Cosmetic Act of 1938. This section requires payment by the owner or consignee of all charges for storage, cartage and labor on any article refused admission, and, in case of default of such payment, they constitute a lien against any future importations made by such owner or consignee.[77]

Regulation 27 of the Act of 1906,[78] dealing with exports from the United States, became Section 801 (d) of the Act of 1938.

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[75] Act of June 22, 1934, 48 Stat. 1204, as amended by Act of August 27, 1935, 49 Stat. 871, 21 U. S. C. 372a, Supp. 1938.

[76] Section 902 (a), Federal Food, Drug, and Cosmetic Act of 1938.

[77] 7 U. S. C. 134.

[78] Export section upheld — *Philadelphia Pickling Co. v. United States*, 202 Fed. 150. Notices of Judgment 2456 (1913). *United States v. Catz American Co. Inc.* (1931), 53 Fed. (2d) 425, Notices of Judgment 19276.

A fairly new development in the import field is the establishment of Foreign Trade Zones,[79] or Free Trade Zones, as they are popularly called, and such zones have been established in New York and New Orleans (1947), and others are contemplated.

Section 101 of Article 1, Definitions, describes a zone as follows:

"A zone is an isolated, enclosed, and policed area, under the supervision of a designated board of Federal officials, operated as a public utility by a corporation, in or adjacent to a port of entry, without resident population, furnished with the necessary facilities for lading and unlading, for storing goods, and for reshipping them by land and water; an area into which goods may be brought, stored, and subjected to certain specified manipulation operations. If reshipped to foreign points the goods may leave the restricted trade zone without payment of duties and without the intervention of customs officials, except under certain conditions. Such products cannot, of course, leave the trade zone for domestic use or consumption without full compliance with existing customs laws. Goods may not be manufactured or exhibited in such an area. The area is subject equally with adjacent regions to all the laws relating to public health, vessel inspection, Postal Service, immigration, and to the supervision of Federal agencies having jurisdiction in ports of entry, including customs, to a limited extent."

The Foreign Trade Zone was created for the purpose of stimulating foreign trade but the zone is not extra-territorial. Permission to manipulate shipments in the zone must be obtained from the Collector of Customs, who can refuse the request if the requested manipulation is not authorized by the Act. Merchandise which is prohibited by law may not be admitted to a zone, and a detained shipment of foods, drugs, devices, or cosmetics may not be admitted to a zone. Narcotics may not be admitted except those required for emergency medicinal purposes, and, if found in a zone, they may be seized. Authority to examine goods in a zone is granted to the appropriate officers.

The law grants authority to an importer to store, break up, repack, assemble, distribute, sort, grade, clean, or mix merchandise with foreign or domestic merchandise or otherwise manipulate merchandise in a zone,[80] but prohibits manufacture and exhibition of the goods,[81] and the Board may order the exclusion of any goods or process of treatment that in its judgment is detrimental to the public interest, health or safety.[82]

The development of the foreign trade zone was greatly impeded by the recent World War, as normal import traffic ceased, and because,

[79] Act of June 18, 1934 (48 Stat. 998, 1001), Public No. 397, Seventy-third Congress.

[80] Section 3, Public No. 397, of the Seventy-third Congress.

[81] Section 3, Public No. 397, of the Seventy-third Congress.

[82] Section 15 (c), Public No. 397, of the Seventy-third Congress.

also, the Navy occupied a large part of the facilities of the zone at New York; thus not many procedural questions or questions of rights of importers and government have arisen or been determined. As use of such zones increases, we shall perhaps see some jurisdictional complications. These undoubtedly will be solved in a way to effect the fundamental purpose of the zones, the facilitation of international trade without sacrifice to the welfare of the American public.

Insofar as enforcement of the import sections of the Federal Food, Drug, and Cosmetic Act is concerned, the creation of the foreign trade zone has not greatly affected it, and not adversely. A few shipments have been reconditioned and blended, but these operations could have been performed in foreign lands. Since deliberate adulterations cannot be carried out in a zone, enforcement of the Food, Drug, and Cosmetic Act should be facilitated, as it is obvious that a better check can be maintained over operations in the zones than could be exercised in foreign countries. The growth of use of the foreign trade zones can require an increase in import control activity, since a large lot of an imported product can be put into a zone and then, after manipulation, be entered into the United States in a great number of small parcels, requiring a separate examination of each. An importer could thus keep turning his money over paying the duty on each lot with the proceeds of the sale of the previous lot. If entered as a whole, duty on the whole lot would be due at one time.

It is expected that a bill broadening the scope of the foreign trade zone will be introduced in Congress at its next session.

Federal Food, Drug, and Cosmetic Act

The major act covered by this paper is the Food, Drug, and Cosmetic Act,[83] passed on June 25, 1938. This act is the act of the widest scope, regulating the importation of foods, drugs, and cosmetics into the United States.

By 1933, it was well recognized that the pioneer act of 1906 was in need of modernization, strengthening, and enlargement. It contained no provisions relating to cosmetics, and there were on the market certain eye-lash dyes which in many cases blinded the young women

[83] 52 Stat. 1055, 21 U. S. C. 371 (a), Reorganization Act of 1939 (53 Stat. 561ff), 5 U. S. C., Supp. V, 133ff, and Reorganization Plan No. IV (54 Stat. 1237), 5 *Federal Register* 2421, as amended.

who used them; it was incapable of preventing the marketing of untried new drugs, and its penalties for violations were too ineffectual. Efforts were made to remedy the situation by the passage of a new act.

In 1933, Senator Royal S. Copeland of New York introduced a bill recommended by the United States Department of Agriculture. It was largely the work of Mr. W. G. Campbell, Chief of the Food and Drug Administration, and a small group of associates. It was not until 1938, following the pathetic tragedy of the poison elixir sulfanilamide which cost over one hundred lives, that Congress passed the Food, Drug, and Cosmetic Act. During these five years, the proponents of new food, drug, and cosmetic legislation never stopped fighting for an effectual act. They fought almost alone, as little or no publicity was ever given to their cause and they had no aroused public opinion such as existed in 1906. Many bills were introduced, fought over, and dropped or changed. The bill that finally was enacted into law contained many compromises, but was a remarkably effective act, nevertheless. To the means of enforcement by criminal prosecution and seizure, there was added a third, the injunction. Cosmetics were brought under the act, and a "new drug" section was added as a safeguard against the repetition of a new elixir sulfanilamide-type disaster.

History had repeated itself; Mr. Campbell had reenacted the role played by Dr. Wiley many years before. He, too, had won his battle!

This Act has been amended several times during the nine years of its life to cover insulin,[84] penicillin,[85] and streptomycin,[86] and importations of these products must comply fully with its requirements before entry is permitted.[87]

Section 801 is reproduced in full. Space will not permit insertion of the regulations, which will be found in Service Regulatory Announcement, Food Drug Cosmetic 1, Revision 2.

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[84] 55 Stat. 851, 21 U. S. C., Supp. V, 356. Latest regulations, 12 *Federal Register* 2226-2231, April 4, 1947.

[85] 59 Stat. 463, 21 U. S. C., Supp. V, 357. Latest regulations, 12 *Federal Register* 2231-2248, April 4, 1947, and 12 *Federal Register* 6109, September 13, 1947.

[86] Public Law 16, Eightieth Congress, Chap. 16, first session (House of Representatives 2045), 21 U. S. C., Supp. 357. Latest regulations, 12 *Federal Register* 2231-2248, April 4, 1947, and 12 *Federal Register* 6109, September 13, 1947.

[87] The Food and Drug Administration has ruled that Regulation 2.13 (b) under Section 405 and Regulation 2.107 under Section 503, dealing with processing, labeling and repacking of foods and drugs, do not apply to import shipments.

"Sec. 801 (a). The Secretary of the Treasury shall deliver to the Federal Security Administrator, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Federal Security Administrator and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 505, then such article shall be refused admission. This paragraph shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under section 2 of the Act of May 26, 1922, as amended (U. S. C., 1934 edition, title 21, sec. 173).

"(b) The Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any such article refused admission, unless such article is exported by the consignee within three months from the date of notice of such refusal, under such regulations as the Secretary of the Treasury may prescribe: Provided, That the Secretary of the Treasury may deliver to the consignee any such article pending examination and decision in the matter on execution of a bond as liquidated damages for the amount of the full invoice value thereof together with the duty thereon and on refusing for any cause to return such article or any part thereof to the custody of the Secretary of the Treasury when demanded for the purpose of excluding it from the country or for any other purpose, such consignee shall forfeit the full amount of the bond as liquidated damages."

The procedure governing the examination, admission, and exclusion of imports was so little changed by the 1938 Act that a discussion of it under both acts is given at this point (with appropriate notes on differences). The procedure is almost wholly administrative, and neither statute provided for judicial review. However, judicial review is possible in two ways:

(1) The government, through its Collectors of Customs, may bring an action on the importer's bond to collect as liquidated damages the full amount of the bond for illegal disposition of an import shipment or for failure to return it to Customs custody on demand by a Collector of Customs.[88]

[88] *Bond Action Cases* under Food and Drugs Act: Food Notices of Judgment 25055, *United States v. King and Howe Inc. and Royal Indemnity Co.* Suits instituted for invoice value of three lots of imported stramonium leaves which had been entered under term entry bond and subsequently found to be adulterated in violation of the Food and Drugs Act of 1906. The importer failed to redeliver the goods for exportation or destruction on demand by the Collector of Customs, and the government instituted suit to collect the full value of the bond, $8,381.43. Verdicts and judgments for the government affirmed by Circuit Court of Appeals for the Second Circuit on July 16, 1935.

Under Food, Drug, and Cosmetic Act—no cases.

(2) The importer may bring an injunction suit against the Collector of Customs and the Food and Drug Administration Station Chief of the same port in an attempt to restrain them from excluding his shipment.[89]

Each law contains a provision for the posting of a bond,[90] to the extent of the value of the shipment plus the duty thereon, by the importer, who could then take delivery of the merchandise, holding it in the port of entry until released by the Food and Drug Administration, and the refusal by the importer to return the shipment to the custody of the Secretary of the Treasury on demand for the purpose of excluding it from the country, or for any other purpose, is the basis for the forfeiture of the full amount of the bond.

The provision is required by practical reasons; it avoids congestion on the piers, and it allows an importer to protect his merchandise by proper storage during the period required by the sampling operation and subsequent analysis and examination of the sample. It has one outstanding disadvantage, since the goods are put into the hands of importers prior to examination and a determination of fitness for use, and an unscrupulous importer can distribute them with serious harm to the public, if adulterated, and, unless he further ships them in interstate commerce, he is liable only to a money penalty insofar as the Federal Act is concerned; that is, the amount of the entry bond.

Commercial success in an import transaction often depends on the speed of marketing the goods after arrival in the United States, and importers sometimes distribute their goods immediately on receipt without awaiting a determination by the Food and Drug Administration of compliance with the law. This constitutes a definite redelivery bond violation, and actions on such bonds are taken at the rate of several per week at the Port of New York alone.

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[89] Under Food and Drugs Act: *Ambruster v. Mellon*, 41 F. (2d) 430 (App. D. C. 1930); *Knapp v. Calloway*, 52 F. (2d) 476 (DC N. Y. 1931); *Knapp v. Hyde*, 50 F. (2d) 272 (DC N. Y. 1931); *Davis Milling Co. Inc. v. The Secretary of Agriculture*, Equity No. 320, (DC Va. 1934); *Davis Milling Company, Inc. v. I. Walke Truxtun, Collector of Customs of the United States for the Eastern District of Virginia et al.*, Equity No. 403 (DC Va. 1938).

Under Food, Drug, and Cosmetic Act: *John T. Bowman, Master of S.S. James J. Hill v. Allen T. Retzlaff, Baltimore Station, Food and Drug Administration of Federal Security Agency and George T. Cromwell, Collector of Customs, Port of Baltimore*, 65 F. Supp. 265. This was an injunction suit brought by an importer in the District Court for the District of Maryland to restrain the government from enforcing its order requiring exportation or destruction under customs supervision of an adulterated lot of wheat. Dismissed.

[90] The bond was called a penal bond under the Food and Drugs Act of 1906, and is called a bond as liquidated damages under the Food, Drug, and Cosmetic Act, but this has had no effect on bond actions.

When bond actions are begun, the Secretary of the Treasury is authorized to compromise settlements, and, since repeated bond actions are instituted against the same importers, it may be assumed that previous settlements have not been sufficiently severe to act as deterrents.

The public can be protected by Federal, state, and city seizures of adulterated goods distributed by an importer prior to a release by the Food and Drug Administration, but this would involve a great deal of regulatory work, since in most cases import shipments are large and are widely distributed. It would be much simpler, and it would afford greater public protection, if all imports were required to be put into bonded warehouses until released by the Food and Drug Administration, as is the case with tea shipments. This would require new legislation by Congress. Furthermore, when the goods are allowed to be placed in the hands of the importer prior to inspection by the Food and Drug Administration (this period may be several days), substitution and manipulation are possible. Identification of many shipments is difficult in any case, and, when shipments are stored near other similar goods or unpacked from the original containers, the government is at a distinct disadvantage in discovering such chicanery. For example, who could say for certainty that a box of whitefish pointed out to him as the shipment involved contained the whitefish covered by a particular entry?

I do not mean to imply that the import business as a whole is corrupt. On the contrary, the vast majority of importers handle their shipments quite properly, but there is a minority fringe that will take unfair advantage if the situation permits. Twelve years of experience as an import enforcement officer has convinced me that the changes suggested are now required for the full protection of the American public. They would make it certain that only legal imported foods, drugs, and cosmetics reached the American consumer.

Although the language of Section 11 of the Food and Drugs Act plainly stated that the Secretary of Treasury shall furnish to the Secretary of Agriculture samples of import shipments of foods and drugs requested by him, and Section 801 (a) of the Food, Drug, and Cosmetic Act likewise states that

"The Secretary of the Treasury shall deliver to the Federal Security Administrator upon his request, samples of foods, drugs, devices and cosmetics which are imported or offered for import into the United States. . . ."

in actual practice under the Food and Drugs Act of 1906, the Food and Drug Administration drew its own samples in those ports where Food and Drug Administration stations were located, and requested samples from the Customs Officials when entries were made at non-laboratory ports, and follows the same procedure today under the Food, Drug, and Cosmetic Act.

From this point on, I shall discuss the procedure as it exists today under the Food, Drug, and Cosmetic Act.

An import shipment of a food, drug, device, or cosmetic arrives at a United States Port by ship,[91] rail, or by air.[92] The owner, directly or through his customs broker, makes one of the several types of entries subjecting his goods to inspection at the port of entry by the Food and Drug Administration (Entry For Consumption, Entry For Warehouse, Entry For Appraisement, Informal Entry, etc.), and posts his redelivery bond. A permit is issued by the Customs, and the importer is allowed to take possession of the goods. The invoice is sent by the Entry Division of the Customs to the Appraiser, who immediately submits it to a representative of the Food and Drug Administration if the entry covers shipment of merchandise from which no units will be brought into Public Stores, or he withholds it until such units are brought in (in those instances) and submits it to the Food and Drug Administration together with the units brought into Public Stores. At New York, upon receipt of the invoice, the Food and Drug Administration representative takes one of two actions.

(1) He may release the shipment without examination, by stamping the invoice and attached notice to the importer, which is returned to the importer with a stamp reading, "No Sample Desired—Date" Initials of representative. The importer is then free to dispose of his shipment.

(2) He may direct sampling of the shipment, or he may take a sample from the Public Store's units submitted to him (as the case may be), and if so, he performs five acts:

(a) He attaches a sample notice to the invoice for purpose of notification to the Customs of his action.

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[91] For Ports of Entry, see Customs Regulations, Part 1.

[92] Importation by Air. See Air Commerce Act of 1926, 49 U. S. C. 177 (b), as amended, and Part 6, Customs Regulations, for ports of entry of civil aircraft and general regulations.

(b) He indicates his intention to sample on the notice to the importer, and returns it to the importer's box in the Appraisers Stores, at the same time marking thereon the Food and Drug reference number.

(c) He prepares an import sample report in duplicate.

(d) He posts the entry number of the shipment on the bulletin board located in the Appraisers Stores.

(e) He prepares a formal sample notice to be mailed to the importer of record. All notices except (b) are required by the regulations. The use of the notice under (b) saves from ½ day to 1 day for the importer.

Next, the shipment is assigned to the Wharf Sampler force for sampling, if the Floor Examiner did not take samples from the Public Stores cases. The samples are submitted to the station laboratory which usually analyzes them, or sends them to the specialized laboratories in Washington, D. C., if required. Bacteriological examinations, vitamin assays and bio-assays are examples of the work done in Washington.

If the laboratory and wharf examinations disclose no adulteration, and the labeling is also in compliance with the Act, the shipment is released, and the importer is sent a copy of the release.

Releases may be of four types:

(1) Outright release, issued when no violation is disclosed.

(2) Release without prejudice to future actions in similar instances, which is used where there is a doubt as to the legality of the shipment. It serves as a warning that action will very likely be taken against future similar shipments when the required facts have been obtained.

(3) Release with warning is used where the violation is of a minor character, usually a minor misbranding. With such a release, a letter is written to the importer, explaining the violation and instructing him to so inform the shipper, and requesting proof that he did so inform the shipper. It further warns that, in all future cases, after the shipper has had time to correct his labels, shipments in violation of the Act in the same manner will be detained.

(4) Release without examination. It sometimes happens that pressure of work means that a few shipments have to be released without analysis in order to avoid an undue delay in action.

Even though an import shipment is initially released on entry, it may be seized and removed from the market if it was either adulterated or misbranded on arrival and the goods are no longer in Customs Custody.[93] If the entry has not been liquidated, then the former release may be recalled and a detention issued. It may also be seized if it was legal on arrival, and later became adulterated or misbranded and subsequently shipped in interstate commerce. The public welfare requires this protection since food and drug and cosmetic products may deteriorate or be deliberately adulterated or misbranded after arrival at a United States port.

Shipments which have been detained and required to be exported, and which are offered for entry again, are seized, rather than detained, and in this case exportation is not permitted. Commerce between a foreign country and the United States is interstate commerce [94] by definition, and the Act prohibits the interstate shipment of adulterated or misbranded foods, drugs, devices, and cosmetics,[95] and subjects them to seizure.[96]

The Food and Drug Administration is of the opinion that foreign shippers can be criminally prosecuted for deliberate violations of the Food, Drug, and Cosmetic Act, such as the reentry of merchandise which had previously been entered at a United States Port, found to be in noncompliance with the Act, and required to be exported. The Administration has recently obtained a grand jury indictment against a shipper in such a case. Of course, service must be made on the defendant while he is within the Federal jurisdiction.

If, however, the shipment is found to be adulterated or misbranded, it is detained, and the importer is sent a copy of a Notice of Detention and Hearing, which requires an appearance in person or a written response within three days. The notice sets forth the section of the law it is alleged the shipment violates, and sets forth the reasons for the charge. If the notice remains unanswered, another copy of the notice

[93] *United States v. 165 Bags of Mustard Seed*, Notices of Judgment 20065 (1932). *United States v. 9 Barrels of Olives*, 179 Fed. 983, Notices of Judgment 648 (1910). *United States v. 5 Cases of Mace*, Notices of Judgment 7619 (1945). *United States v. 35 Bags of Nutmegs*, Notices of Judgment 8986 (1945).

[94] Section 201 (b), Federal Food, Drug, and Cosmetic Act.

[95] Section 301 (a), (b), (c), Federal Food, Drug, and Cosmetic Act.

[96] Section 304 (a), Federal Food, Drug, and Cosmetic Act.

marked "Second and Last Notice" is sent to the importer, and if this notice also remains unanswered, Form 776-a, requiring exportation or destruction [97] of the shipment under Customs supervision, and also warning the importer that, if he fails to comply, he is required to return the goods to the Collector of Customs, failure of compliance resulting in action on his bond, is sent to the importer.

The importer appears for his hearing, which is informal, and he is allowed to present any relevant testimony, and he may submit evidence of error in the government's findings, or he may ask for a postponement so that he can have his own analysis made, or so he can consult the shipper, or decide upon his course of action. Postponements are granted for good cause, and reexaminations are granted whenever the importer submits a certificate of an analysis (which reports results different from those of the government) from an independent, qualified commercial laboratory located in the United States, based on an adequate sample and examination, and containing certain required information—that is, sufficient information to identify the shipment, and detailed data on the sampling and examination of the sample, so that a proper evaluation of the work done can be made by the reviewing officer.

Based upon all of the evidence, the shipment may be released, or continued under detention, or denied entry. If denied entry, the shipment is ordered exported or destroyed, as reported in the case of nonappearance at the hearing. Final orders of Station Chiefs may be successively appealed to the Chief of Eastern District, the Commissioner of Foods and Drugs, and to the Federal Security Administrator. Copies of all notices sent to importers are sent to the Collector of Customs.

The importer, in most cases, files an application for a conditional release, under which he is permitted to legalize his shipment by relabeling, segregating, reconditioning, or cleaning under Food and Drug Administration supervision. In some cases, the importer requests permission to divert his shipment into a restricted legitimate technical use. Denaturing may be required, or proof of legitimate use may be required from the users in the form of performance affidavits from such users.

[97] Whenever shipments which have been detained by the Food and Drug Administration are exported or destroyed under Customs supervision, bond liability is discharged and any duty previously paid is refunded. Part 12, paragraph 12.6 (b), Customs Regulations; also 46 Stat. 744, 52 Stat. 1088, R. S. 161, 19 U. S. C. 1588, 5 U. S. C. 22.

The conditional release allows three months to comply with its terms, and, if the shipment has not been legalized or used in the directed manner by the expiration of that period, exportation or destruction under Custom supervision is ordered, failure of compliance resulting in a bond action.

If, however, the work has been done satisfactorily, the shipment is released and the bond liability is discharged after any rejects resulting from the cleaning operations have been destroyed or diverted into non-food and drug uses under government supervision. Rejects may not be exported.[98] If, however, the work has not been done satisfactorily, the shipment is ordered exported or destroyed in its entirety as previously described.

Conditional releases are not provided for under the Act (nor were they provided for under the Food and Drugs Act of 1906), but the procedure was required by practical necessity and it has never been challenged in the courts. The cost of supervision is borne by the Food and Drug Administration. Thus, the conditional release is not a legal right but is a privilege only and it is granted only in appropriate cases. Many shipments cannot be legalized, and applications for conditional releases are refused. They are not granted in cases of intentional, flagrant, or repeated violations.

Violative parcel post or registered mail shipments are required by Postal Conventions to be returned to the sender by the Post Office Department.[99]

At any point in the procedure just outlined, a violation may occur. The importer may remove his shipment from the port of entry prior to sampling. If he does, he is required to return it, and if he does not, a bond action is initiated.

Any use of detained goods prior to release will also result in a bond action. This may occur on delivery to the importer, or may occur during or after reconditioning operations, but prior to final examination by the Food and Drug Administration. Bond actions are also instituted wherever the importer has or claims to have exported or destroyed whole or part of a detained shipment, including rejects from a reconditioning oper-

[98] Administrative ruling. Ruling sustained in *Davis Milling Co., Inc. v. I. Walke Truxtun, etc. et al.*, Equity No. 403 (DC Va. 1938).

[99] See Part 9, Customs Regulations, 39 CFR, Chap. 1, Pt. 22, and also Section 2229 of the Postal Laws and Regulations of 1940.

ation, without Customs supervision, or whenever he has exported rejects from cleaning operations contrary to the terms of the conditional release.

Violations may be discovered by either the Bureau of Customs, or Food and Drug Administration, and a report is immediately made to the other agency. The Food and Drug Administration Station summarizes the facts, lists former violations by the same importer and makes recommendation as to the amount of the penalty. The local collector then reports the case to the Bureau of Customs, which consults the Food and Drug Administration in Washington and then fixes the penalty.

The Food and Drug Administration pays the importer for all samples taken from shipments which are found to be legal on arrival and which are released. However, it does not pay for samples taken from shipments which are detained and found violative, for such shipments are contraband,[100] and the rule extends to these samples taken after reconditioning or relabeling operations as a check on such operations.

In recent years, the Food and Drug Administration has become conscious of the fact that some revision of the import regulations is desirable and is now giving considerable thought to improvements that should be made.

The Food and Drug Administration receives many requests for copies of analyses made by it, on samples taken from imported shipments of foods, drugs, devices, and cosmetics, from importers, shippers and from attorneys, who desire to use them in civil suits arising out of detentions of parcels of imported merchandise. Such analyses are not matters of public record, since they are not final orders within the meaning of the Administrative Procedure Act.[101]

The Administration will, however, instruct its officers to accept *subpoena duces tecum* in certain cases. If the government has closed its own case and feels that disclosure of its records will not adversely affect the public interest or result in the disclosure of confidential matters, the Commissioner of Foods and Drugs will often order disclosure where the person seeking the information has (a) filed a written request, under oath, directed to the Commissioner of Foods and Drugs, setting forth his interest in the matter sought to be disclosed, and (b) specifically

[100] Notice to Importers of Foods, Drugs, Devices, Cosmetics and Caustic Poisons (undated).

[101] Approved on June 11, 1946, as Public Law 404.

designating the use to which records or information will be put in event of compliance with such request. This procedure is required by regulations of the Federal Security Agency.[102]

State Laws

The Supreme Court has laid down the principle that state Food, Drug, and Cosmetic Laws cannot directly conflict with the Federal law,[103] but may supplement it and make additional requirements.[104] In general, the state laws are very similar to the Federal Food, Drug, and Cosmetic Act. In the field of foreign imports, the Federal government is supreme while the goods are still in import status, but when they are released and become part of the common mass of property of a state, then they also become subject to state laws.

Import Activities of Food and Drug Administration

The value to the public of the control of imported products exercised by the Food and Drug Administration acting under the authority of the Federal Food, Drug, and Cosmetic Act cannot be accurately determined. An epidemic may have been prevented, many cases of food poisoning were prevented, possibly deaths from imported sleeping pills were prevented. Who can exactly say what the results were? Positively, though, we do know that over 6,000 illegal shipments were detained last year, including millions of pounds of unclean food and numerous shipments of misbranded and adulterated drugs and cosmetics. The cost to the public was trivial. The cost of enforcing the entire Act amounted to a little less than *three cents per person* for the entire year, the cost of import enforcement being a minor fraction of these three cents.

The following section is a part of the Annual Report of the Federal Security Agency for the fiscal year, 1946. It accurately depicts the import activities of the Food and Drug Administration relating to unfit foods for that year.

"The quality of imports was understandably lower than before the war. The present availability of shipping space brought merchandise from lands that have for a number of years been practically isolated. Excessively long storage meanwhile resulted in deterioration and contamination by rodents and insects. For example, cassia

[102] 10 *Federal Register* 4789, May 2, 1945.

[103] *McDermott v. Wisconsin*, 228 U. S. 115 (1913). State law required removal of labeling required by Federal Statute on containers of corn syrup. State act was held invalid.

[104] *Savage v. Jones*, 225 U. S. 501; *Weigle v. Curtice Bros. Co.*, 248 U. S. 285.

offered for entry from the Orient has been shown to be over 6 years old and nearly 72 per cent of the poundage entered was detained on account of mold, rodent excreta, insects, and manure contamination. In other instances there was grave deterioration of those controls at the source which had rendered products largely nonactionable in prewar years. A third reason for deterioration of quality in imports is the apparent eagerness of foreign shippers to rush into the American market with products prepared by persons inexperienced in meeting American standards, and often working with faulty equipment.

"This is not the place for a tabulation of all of the examinations and detentions comprising the year's import control of foods, but a few high lights will indicate its volume and character, and some of the problems that confronted the wharf examiners, a force still inadequate, despite the fact that it was doubled at New York and increased at other ports where entries have shown a heavy increase.

"Abuses in salvaging coffee sweepings resulted in the referral of over 900,000 pounds to the Collector of Customs for reexportation or destruction. This material had been gathered up from wharf floors and ships' holds after having been stepped on, ground by trucks, and often mixed with all the filthy debris that can accumulate at a busy dock. Notice was sent to coffee importers that where substantial quantities of coffee spill from a bag, the portion not contaminated by contact with the floor may be retrieved, but that any portions that have touched the floor, been swept from wharves or floors or holds of ships, or coffee sweepings shipped as such from foreign ports will be denied entry without recourse or cleaning. In addition to the sweepings denied entry, a total of over 4 million pounds of Brazilian coffee was detained because of excessive boring by insects and live insect infestation.

"Large quantities of manioc meal, or unrefined ground cassava root, have been imported from Brazil as a substitute for cereals in the production of beer and other fermented beverages. More than 3.8 million pounds were detained because of gross contamination by insects and rodent filth.

"Detentions of cocoa beans were highest in poundage, although not in percentage examined. Over 16¾ million pounds (above 9 per cent of examinations) were detained, largely because of mold, but in some cases on account of insect infestation, and in Nigerian cocoa, the presence of goat manure, a condition not previously encountered. Moldy and wormy condition caused the detention of nearly 1,850,000 pounds of sweetened and unsweetened chocolate in 10-pound bars exported from South American countries for manufacturing purposes. Nearly 25 per cent of the total poundage examined was denied entry.

"Imports of spices were nearly double the quantities offered for entry in 1945. As pointed out in the first paragraph of this section, many of the products had been in storage for excessive periods awaiting shipment. Disrupted shipping facilities following cessation of hostilities required further storage at intermediate points, often under conditions that contributed to their unfitness. Careful attention was required for all spice importations, as borne out by the fact that 35 per cent of the poundage offered for entry was detained, in comparison with 17 per cent in 1945, and an average of about 10 or 11 in prewar years. Approximately 16½ million pounds of spices were detained for mold, contamination by rodents and insects, manure, dirt, and water damage.

"Other large import detentions of filthy and decomposed foods included over 1½ million pounds of nuts, comprising 4.6 per cent of the quantity examined; over 1⅓ million pounds of figs, or 27 per cent of the poundage examined; and more than a million pounds of dates, or 3 per cent of those examined. The date detentions

were at New York, where 9 per cent had been detained the previous year. This improvement may be attributed in part to the fact that the first shipments of dates reached the United States earlier than some of the commodities comprising the 1946 imports. If other imports parallel this experience, relief in many phases of the import situation may be anticipated.

"Another war-born situation that was given attention under the import provisions of the act was the disposition of ships' stores comestibles. Since these food articles were reentering the country, they were detained as imports until suitable examination could be made. Many of the ships which had made their last trip and were being decommissioned had been in areas particularly subject to infestation, and their stores, if they were disposed of indiscriminately, would have contaminated sound food in storage in this country. The many hundreds of ships in this class brought back millions of pounds of foodstuffs that required examination. Recommendations were issued in each instance to the port steward and follow-up was maintained to insure proper disposal of unfit foods to prevent reentry into consumer channels. Foods condemned consisted largely of products in the cereal group, such as flour, meal, and breakfast foods, with smaller quantities of deteriorated canned foods, shell and dried eggs, dried fruits, butter, and evaporated milk. Salvage of some of these items for animal feeding purposes was possible; others were diverted to the manufacture of fertilizer. . . . Under the Tea Inspection Act, 94,447,300 pounds of tea were examined, of which 7,466 pounds were rejected."

The report for 1947 has not yet been issued but it will show a material increase in import detentions over 1946 and the present trend indicates a further increase during this fiscal year (ending July 1, 1948).

The import situation remains uncertain and confused. There are still three large sections of the world which have not yet resumed normal trade with the United States, and, if the past is any example, trouble in food and drug shipments from these sections will be encountered when they are resumed.

Conclusion

Finally, from a review of the present Federal laws applicable to foreign foods, drugs, and cosmetics, we are convinced that the importer faces many problems and must deal with quite a number of Federal Agencies; that some simplification is necessary; that there is remarkably little duplication of effort in this field of law enforcement with one exception—each agency has its own sampling force, and some shipments are often sampled as many as three or four separate times. In the last analysis, one cannot escape the conclusion that the public is assured of a very large measure of protection.

[*The End*]

The F-O-R-M-U-L-A-T-I-O-N of Mandatory Food Standards

• • • H. THOMAS AUSTERN * • • •

NOT EVEN THE EXIGENCIES OF WAR diminished the restiveness of Americans over administrative regulation of their economic activities. Within a year after hostilities ceased, Congress passed the Administrative Procedure Act, designed in large measure to curb the arbitrary exercise of delegated Federal governmental powers.[1] Few peacetime statutes confer such broad rule-making authority as does the Federal Food, Drug, and Cosmetic Act of 1938 in its sections authorizing the administrative promulgation of standards of identity, quality, and fill of container for practically all foods. And not many other enactments enjoin compliance by the triple sanction of forfeiture, penal prosecution, and injunction.[2] It is therefore not surprising that the resumption of the food standardization program had immediate effects. It reawakened interest in the process. It drew both unmerited and merited criticism of administrative policies and methods. Among food industry lawyers it invited a fresh scrutiny of these statutory provisions and what has and may be done under them.

For these reasons, one feels less reluctant in responding to an invitation to continue the discussion in the *Quarterly* even after two

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[1] Act of June 11, 1946, Public Law 404, Seventy-ninth Congress, second session. This enactment climaxed more than a decade of agitation. For an excellent bibliography, see Note, 56 *Yale Law Journal* (1947) 670.

[2] Compare White Act for the Alaskan Fisheries, June 6, 1924, c. 272, 43 Stat. 464, 48 U. S. C. 221; Fair Labor Standards Act of June 25, 1938, c. 676, 52 Stat. 1060, 29 U. S. C. 201. Criminal proceedings may be brought for non-compliance with a food standard. *United States v. Lord-Mott Co.*, 57 F. Supp. 128 (DC Md. 1944).

experienced lawyers [3] have expounded the theory and difficulties of standard making, and the Secretary of the Food Standards Committee [4] has spelled out some of the current problems. Here offered for additional criticism are some observations and tentative conclusions which have emerged during eight years' activity in standardization proceedings under the Act.

Illustrations are principally drawn from court decisions and from the food standard administrative proceedings in which the writer has participated.[5] The latter are familiar, and, besides, one naturally hesitates to dissect what other lawyers have done. Judicial opinions and administrative rulings are conventionally regarded as fair game for all.

Any disinterested observer perhaps begins and ends with a feeling of sympathy for the group of men who function under the legalized fiction of the "Administrator." [6] A hundred years ago, it must be remembered, human affairs in peacetime were largely entrusted to three ancient, if not equally honored, professions—the doctor, to cope with bodily ills; the minister, to deal with those of the soul against the day of inevitable failure of the doctor; and the lawyer, to deal with all other professional needs. To a large extent, only the lawyer presumed to practice the arts of government in the legislature or in the courts where rules of conduct were hammered out on the anvil of litigation. The administrative process, either of rule-making or adjudication, was virtually unknown; and the invidious connotations of the term "bureaucrat" were still undeveloped.

Today the lawyer is only one of the many who make regulations. His residual and perhaps nostalgic resentment is understandable when one considers the intrusion into the job of government of chemists, bacteriologists, nutritionists, economists, sanitary engineers, accountants, doctors both medical and philosophical, and many other experts.

[3] Markel, Federal Food Standards, 1 *Food Drug Cosmetic Law Quarterly* (1946) 28; Schneider, The Hazards of Food Identity Standards, 2 *Food Drug Cosmetic Law Quarterly* (1947) 33.

[4] Callaway, Current Problems in Formulating Food Standards, 2 *Food Drug Cosmetic Law Quarterly* (1947) 124.

[5] The apparent emphasis on canned foods, however, does not wholly represent recourse to the familiar. Of the 150 standards of identity, 57 cover canned foods; and *all* of the quality and fill of container standards thus far issued embrace canned products alone. Throughout an effort is made to adumbrate problems of general importance to all foods.

[6] The suggested fiction is not destroyed by the assumption of one Court of Appeals that the Federal Security Administrator is obligated to read the entire record. See *Twin City Milk Producers Ass'n v. McNutt*, 122 F. (2d) 564 (CCA-8; 1941) at 569. Compare *United States v. Morgan*, 313 U. S. 409 (1941). However engaging this assignment might be, it is difficult to believe that it is regularly accomplished by an official of virtual cabinet status taxed with administering nine major bureaus in the Federal Security Agency.

Nor does it assuage the legal discomfort to have it asserted that these people have a peculiar skill in making rules for their fellow men.[7] Thus the lawyer clings to the black arts of procedure, stands adamant against what he calls capricious or arbitrary conduct by these interloping experts, and still controls, or hopes to control, the process of judicial sanctification or excommunication of the administrative act.

Whether or not warranted, this feeling perhaps underlies the reactions of some lawyers to the standard making procedure under the Food, Drug, and Cosmetic Act and the three basic questions they immediately ask about that somewhat unique administrative process. The first is, "What are they doing," i.e., is the action authorized under the statute? The second is often, "Are these fellows entitled to exercise final judgment," i.e., is such wide discretion conferred?[8] (This is in reality a doubt as to whether an administrative expert is better qualified to make rules than any one else, and paradoxically derives support from the Jacksonian theory that anyone who can read and write is equally competent to govern.) The third question is, "Have they acted properly," or according to "due process," or Section 701 of the law, or within the confines of the Administrative Procedure Act? This is the more subtle and important inquiry. It may well become the Achilles heel of the process, whether it is disguised as an inquiry into "reasonableness" or the lack of "substantial evidence," or put as the plainer charge of being arbitrary and capricious.

Yet when the lawyers retreat and admit that the art of *expertise* is perhaps a legitimate mode of government,[9] they must be struck by the difficulty of the issues these chemists and bacteriologists and other administrative experts have to resolve. It is, of course, no secret that the real questions in formulating food standards are not scientific or

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[7] Compare Jackson, J., dissenting in *Securities Exchange Commission v. Chenery* (U. S. Sup. Ct., Oct. Term 1946, No. 81, 1947): "The Court's averment concerning this order that 'It is the type of judgment which administrative agencies are best equipped to make and which justifies the use of the administrative process' . . . is sustained by reliance on that disregard of law which enemies of the process have always alleged to be its principal evil."

[8] For Mr. Markel, this is the touchstone for resolving most legal questions relating to standard making, i. e., that "the Administrator, and not the court or jury, must determine the question." Markel, A Postscript to the Papers of the Second Annual Meeting of the Section on Food, Drug and Cosmetic Law, 2 *Food Drug Cosmetic Law Quarterly* (1947) 225. But compare Coleman, J., in *United States v. Lord-Mott Co.*, 57 F. Supp. 128 at 130 (DC Md. 1944).

[9] Professor Laski has some doubts about giving experts the power of ultimate decision. Laski, The Limitations of The Expert, 162 *Harper's Magazine* (1930) 101. reprinted in Gellhorn, *Administrative Law* (1947) 60.

technical but ultimately economic and political.[10] In their earlier papers, Messrs. Markel and Schneider agreed that public health and safety are not concerned in a standard of identity, quality, or fill of container for a food product. The statutory guide of "promoting honesty and fair dealing in the interest of consumers" involves what the latter terms "fraudulent practices" and the former denominates "abuses of the consumer's pocketbook" and the promotion of "methods of fair competition." [11]

The real difficulty lies deeper—in the Congressional attempt to ordain adherence to unregulated competitive enterprise and at the same time to confer wide administrative discretion to regulate under the vaguest of statutory standards. The lawmakers in debate and report subscribed to the familiar article of political faith that free and rugged competition was worth-while; and insisted that the rules always be "reasonable" enough to permit the continued play of competitive forces. Yet they finally legislated that economic standards can be administratively prescribed closely enough to outlaw Farina enriched in one way but not in another.[12] The "priceless ingredient" in an individual brand name is to be recognized, but at the same time the administrative experts must by reasonable rules somehow separate the commercial sheep and goats.

Within this sensitive and explosive *economic* area, the collective group serving the Administrator must act, as Mr. Markel suggests, to "weigh and balance consumer and industry interests" according to the

[10] An economic judgment remains one, no matter how much technical clothing it wears. How to determine the fat or moisture content of cheese, or the specific gravity of tomato puree, are technical questions. Where to put the permissible level of moisture, or what label name to prescribe for a product, or whether a cheaper ingredient may be substituted for a more expensive one, are questions largely answered by economic judgments. With all deference, one need not be a chemist or bacteriologist, and might even be a lawyer, in order to exercise judgment as to what will "promote honesty and fair dealing in the interest of consumers." It is because these are not objective technical questions, but rather issues as imponderable as any in the field of government, that their resolution is often so difficult.

[11] Schneider, The Hazards of Food Identity Standards, 2 *Food Drug Cosmetic Law Quarterly* (1947) 35; Markel, Federal Food Standards, 1 *Food Drug Cosmetic Law Quarterly* (1946) 29. "Honesty and fair dealing in the interest of consumers is closely related to the regulation of unfair competition." Callaway, Current Problems in Formulating Food Standards, 2 *Food Drug Cosmetic Law Quarterly* (1947) 138.

[12] Compare the language of the Senate report of 1935 and the Presidential message of March 22, 1935, advocating new legislation: The former recited that, "The operation of this provision [standard making] will in no way interfere with the marketing of any food which is wholesome but which does not meet the definition and standard . . ." Senate Report 361, Seventy-fourth Congress, first session, March 26, 1935, p. 11. The latter insisted that, "Only the scientific and disinterested activity of government can protect this honor of our producers and provide the possibility of discriminating choice to our consumers." House Document 142, Seventy-fourth Congress, first session, p. 1.

statutory prescription. Of course, unless the rule prescribed is meaningless, it operates to restrict somebody. It hits his pocketbook and usually his pride. His injury is often a matter of arithmetic—and sometimes is backed by a business history of product acceptance—whereas the consumer benefit may be only a matter of the government expert's judgment. Yet few concern themselves with polemics about bureaucracy, and apart from the heat of a particular controversy most will readily grant that better or more devoted public servants than those in the Food and Drug Administration are seldom found. The businessman's candid, "That's their job," is usually the final comment and unconscious praise.

Still the task of deciding these subtle issues is not easy—even when carried on behind the semantic curtain of an ultimate Administrator. It requires a high degree of objectivity and a profound sense of judgment—no matter how skillfully the buttressing findings and conclusions may be drawn. It must be wholly free from personal bias and political or economic predilection—which is a lot to demand of any human being. Objectively viewed, the work these men must do should evoke an understanding sympathy as well as the legal scrutiny which it so often attracts and which this paper continues in the old tradition.

One final introductory caveat seems desirable: Any one individual's generalizations, limited by the horizons of his own data and experience, are apt to be unreliable. Inevitably they reflect and emphasize only those things which have loomed large to him, and may unconsciously be only a caricature of the real picture.

I

> ". . . a reasonable definition and standard of identity . . ."

Much of the litigation and a large part of the criticism of the food standardization program flowed from the apparent failure of many to appreciate at the time the law was enacted in 1938 what the effect of a standard of identity might be. It was generally understood that to "promote honesty and fair dealing in the interest of consumers" [13] the Administrator could promulgate "for any food . . . a reasonable definition

[13] This phrase originated in the McNary-Mapes Amendment of 1930, authorizing minimum standards of quality for canned foods alone. Its history and relation to the 1938 Act are examined in Part II.

and standard of identity" as Section 401 provided. In doing so, he would use "the common or usual name so far as practicable." The identity standard would afford a yardstick against which economic adulteration could be measured. In all likelihood, many believed, only a few of the simpler foods, such as canned vegetables, would require a standard of identity, or minimum quality, or fill of container. All other foods, particularly manufactured products, would be required by Section 403(i) merely to list their ingredients. For many this view was buttressed by the reference in Section 403(i) to "fabricated" foods.

Startling to this group was the scope of the standardization program reaching at an early date such products as fruit cocktail, cocoa derivatives, cheeses, macaroni, self-rising flour, and even bread. Novel seemed the notion that the enrichment program might make two foods exist and require two standards instead of one—leaving some products unanchored to either standard. More important was the realization that authority to prescribe both the ingredients and the label name of a food—for basic and so-called optional ingredients alike—could have important economic impact on those who manufactured the product or supplied its ingredients, as well as upon their competitors. Even today there may be manufacturers in the food industry who remain unaware that this program can include their products.

But most provocative was the view, early advanced, that under this Act the promulgation of a standard of identity could mean (1) that a food product truthfully and informatively labeled might still be outlawed because it did not conform to the standard; and (2) that the inclusion of a wholesome and indeed beneficial ingredient in a standardized food might be forbidden. These results flowed from the interpretation of one paragraph of the misbranding section which was said to mean that any product which to the consumer looked like and tasted like, or was otherwise indistinguishable from, the standardized food would be misbranded if it failed to conform to the standard. But whereas other types of misbranding could be remedied by proper branding and labeling (or perhaps reforming or refilling the package), this kind of misbranding was incurable; the product could *never* be lawfully sold no matter how labeled.[14]

[14] Except for the as yet undetermined possibility of export sale pursuant to Section 801 (d).

As a necessary corollary, once a standard is established, no newly developed ingredient can be added nor can any change in composition, however desirable, be made without further administrative action.

This concept of "exclusive appropriation" of a name to a product whose composition is fixed by Federal regulation—and cannot be varied except by further regulation—is the source of many of the diatribes directed at these provisions of the Act. It likewise underlies the legal attack and public criticism of the process. This is variously expressed as fear that food standards may freeze the processing art, stifle research, or lay the dead hand of bureaucracy on progress in the food industry.[15]

Yet cold analysis of the statute enacted nine years ago suggests that on the two basic issues—the irrelevance of adequate labeling on whether a food not conforming to the standard can be sold; and the propriety of excluding a wholesome ingredient at the outset and all new ingredients not initially recognized—the Food and Drug Administration has only carried out the Congressional mandate. Perhaps of greater significance is the record of judicial approval. Brief analytical review of both points is still warranted. An understanding of how far the basic authority extends is necessary background. It emphasizes the importance of the limitations and procedural safeguards which elsewhere appear in the statute; and it makes appropriate those criticisms, made by friendly critics, which administrative officials possessed of such wide powers ought to welcome.

A. *The "Exclusive Appropriation" Concept*

Frequently, as Mr. Justice Frankfurter has suggested, it is necessary to fashion "a mosaic of significance out of the innuendoes of disjointed bits of statute." [16] Both the labeling issue and exclusion of ingredient question turn on the meaning of Section 403(g). This prohibits the sale of any food which *"purports to be"* or *"is represented as"* the standardized food and does not conform. If Farina With Added Vitamin D could be considered neither as purporting to be nor represented as standardized Farina, and thus could be lawfully sold, it would make no difference

[15] See Peters, Are Food Standards Assets or Liabilities?, 18 *Food Industries* (1946) 1180, 1316.

[16] Frankfurter, Some Reflections on the Reading of Statutes, 47 *Columbia Law Review* (1947) 538. Mr. Justice Frankfurter quotes Cardozo's remark that "the meaning of a statute is to be looked for, not in any single section, but in all the parts together and in their relation to the end in view." *Panama Refining Co. v. Ryan*, 293 U. S. 388, 433, 439 (1935).

whether Vitamin D by itself was or was not recognized as a permitted optional ingredient in Farina.[17] The narrow question is what effect Congress intended Section 403(g) to have.[18] If it is only another means of securing truthful and informative labeling, any food of any composition may lawfully be sold if properly labeled, even though it looks like the standardized food and tastes like it.

The early approach was by way of legislative history and only occasionally by examination of what the statute said. So often was the legislative paternity explored, that what was reasonably clear from the text of the Act sometimes became obscured. The usual argument (incidentally well founded in much that had been said by some at the legislative hearings) was that the fundamental purpose of an identity standard was to provide a yardstick against which ecomonic frauds could be measured. These are prohibited in Section 402(b) and embrace the omission of a valuable constituent, the substitution of a poorer ingredient, the concealment of inferiority, or any manipulation of a food which may "reduce its quality or strength, or make it appear better or of greater value than it is." Obviously, such prohibitions derive meaning only when measured against some standard, and to this extent the argument is valid.

Yet if this were all that standards of identity promulgated under Section 401 were intended to accomplish, there would have been little need for Section 403(g). With a standard promulgated, economic frauds of the type interdicted in Section 402(b) would have been adequately covered.

Nor is there any doubt that practically all types of label misrepresentation could have been dealt with under the misbranding section without recourse to subsection (g). *Any* labeling which is false or misleading in *any particular* is prohibited. (Sec. 403(a).) A food offered for sale under the name of another food is misbranded. (Section 403(b).)

[17] It is only fair to report that this question was not always clear to those who administered the Act. In one of the earliest standard hearings, that on Canned Peas, evidence on the use of artificial coloring as an optional ingredient was at first refused admission on the ground of irrelevancy. The hearing officer thought that artificial coloring might be added to any standardized food. This view was changed prior to the close of the hearing.

[18] The issue is seldom so nakedly posed. More frequently there is discussion of the basic purposes of the law in somewhat general terms. Usually this is to the effect that the adulteration provisions are to insure proper sanitation, the misbranding provisions to safeguard honesty in marketing, and the standard provision to insure the integrity of food products.

And even physical simulation—a food which looks like or tastes like the standardized food but does not conform to the standard—was probably comprehended in the requirement that a food which imitated another food had to be labeled "imitation."[19]

The significant thing is that Section 403(g) went further. Congress banned the sale of any food which "purports to be," as well as one which was "represented as," a food for which a definition and standard of identity has been prescribed if the product did not conform to the standard. The dichotomy between "purports to be", i.e., which simulates, and "represented as," i.e., mislabeled or presented as, is not sharply drawn. Each of these phrases must be given meaning: A food which does not conform to the standard can be "represented as" the standardized food either because it is so labeled, or possibly even because it looks like the standardized food and is in practice substituted for it.[20] Similarly, a food can "purport to be" the standardized food either because it is so labeled or because it closely simulates the standardized food in appearance. The point is nicely illustrated in the *Tomato Catsup* case,[21] where two courts concluded that "Tomato Catsup With Preservative" was labeled so as to be represented to be catsup, was physically indistinguishable from the standardized food catsup, and was in fact accepted by consumers as catsup.

Necessarily, if the Act aimed only at labeling, the prohibition of the sale of one food under the name of another in Section 403(b) might have sufficed. And careful and adequate labeling, with sufficient information to convey truthfully the actual differences, might have avoided misbranding. Likewise, if simulation alone was deemed undesirable, the requirement of labeling as "imitation" would have answered the need.[22]

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[19] The departure from the standard would have had to be less in degree than those prohibited as adulteration under Section 402 (b), and presumably could have been adequately disclosed by labeling as an "Imitation" with disclosure of ingredients.

[20] The term "label," under Sections 201 (k) and (m), must be taken to include both what is displayed on the container or wrappers and any literature accompanying the package.

[21] *Libby, McNeill & Libby v. United States*, 148 F. (2d) 71 (CCA-2; 1945), affirming 55 F. Supp. 725 (DC N. Y. 1944).

[22] This is not wholly to disregard the infirmities of the old advisory standards under the 1906 Act or the breaches which the "distinctive name" provision in the old law made in the regulatory wall. The latter difficulty in great measure was remedied by Section 403 (i) requiring listing of ingredients and the designation of the common or usual name on unstandardized foods. The fact that ingredients in a standardized food may by regulation *not be listed* contributes to the force of the suggested analysis of the entire Act.

Either there was unnecessary overlapping and unbelievably inartistic draftsmanship, or Congress in Section 403(g) was seeking to do more. Legislative tautology generally cannot be, and in this instance has not been, accepted. The standards of identity were intended to answer some purpose beyond that of ensuring truthful and informative labeling.[23] Thus, on the face of the statute, and from a consideration of its entire text—without resort to the supposed revelations of legislative history—the conclusion is compelled that a standard of identity aims at what a Government witness once called in a hearing "fundamental deceptions [not] correctible by any form of label statement." [24] As Mr. Callaway has put it: "Basically, this purpose, in the case of definitions and standards of identity, is to assure the consumer of obtaining a worth-while article without the necessity of studying and interpreting the labeling to find out what is being purchased." [25]

To escape momentarily from the confines of the statutory text, this amounts to saying that in formulating a standard of identity the Administrator may with propriety assume that people do not read labels —that administrative action "to promote honesty and fair dealing in the interest of consumers" may proceed on the basis that these portions of the Act are designed "to protect the public, the vast multitude which includes the ignorant, the unthinking, and the credulous who, when making a purchase, do not stop to analyze." [26] If this is correct, then perhaps some reorientation of thinking about what the statute does or

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[23] Another instance of the interrelation of statutory provisions can be found between Section 403 (h) (2), requiring conformance to a standard of fill of container, and Section 403 (d), which makes misbranded any food whose container is so made, formed *or filled* as to be misleading. To enforce Section 403 (d), a standard of fill is desirable though not essential. With a standard of fill, Section 403 (d) might have been thought sufficient. Yet Section 403 (h) (2) contains the additional prohibition against violation of the fill of container standard. Compare Interpretation On Large Canned Oysters, February 3, 1947, *CCH Food Drug Cosmetic Law Reports* ¶ 7036.

[24] See *Land O' Lakes Creameries v. McNutt*, 132 F. (2d) 653 (CCA-8; 1943) at 656. Were it necessary to pursue the argument, it could be urged that unless Section 403 (g) means exclusive appropriation of a name to products of specified composition, the references in the Act to "optional ingredients" would lose most of their meaning. If the product containing ingredients A, B, C, and D were standardized as *ABCD*, and yet other ingredients could be added, with the label *ABCD With X and Y*, there would have been little need to be concerned with optional ingredients. The only effect might have been that recognition of X and Y as optional ingredients might have eliminated label reference if the Administrator permitted. In practice, this is rarely permitted except for minor ingredients which facilitate processing.

[25] Callaway, Current Problems in Formulating Food Standards, 2 *Food Drug Cosmetic Law Quarterly* (1947) 138.

[26] *United States v. 62 Packages*, 48 F. Supp. 878, 887 (DC Wis. 1943). One cannot assume that the consumer has access to the Federal Register and can determine what the standard prescribes. Moreover, it is doubtful whether standard drafting has reached this level of lucidity.

does not authorize may be necessary, and closer examination of what is done and how it is done, rather than the ultimate purpose to which it relates, will be warranted.

Any further legal argument seems foreclosed by the Supreme Court decision in the *Quaker Oats* case.[27] Despite almost ten years of debate about legislative history, and abundant resourcefulness by participating counsel, it is now clearly settled that the wholesomeness or beneficial character of any excluded ingredient, or the ease or difficulty with which labeling might reveal differences, is not controlling in administrative standard making. The Supreme Court has said that in Sections 401 and 403(g) the purpose of the Act

"was not confined to a requirement of truthful and informative labeling".

but was to

"reflect a recognition by Congress of the inability of consumers in some cases to determine, solely on the basis of informative labeling, the relative merits of a variety of products superficially resembling each other".

Moreover, the Court rejected the views of a lower court that the sale of a standardized product, Enriched Farina, "whose labels were not required to disclose their ingredients," might be indeed more confusing than a product labeled Farina Wheat Cereal Enriched With Vitamin D whose ingredients were fully disclosed by "an accurate and informative label." [28] On the question of what may confuse the consumer, the courts cannot substitute their judgment for that of the Administrator where there are the requisite findings based on substantial evidence.

Thus the Administrator may by a standard of identity go so far as to exclude a harmless or even beneficial ingredient where he concludes that, despite truthful and fully informative labeling, doing so will promote honesty and fair dealing for consumers. The result is that the product cannot be lawfully sold if it so closely simulates the standardized food as to permit confusion or passing off or substitution. Yet, though this is the ambit of his authority, the Administrator's discretion in reaching a

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[27] *Federal Security Administrator v. Quaker Oats Co.*, 318 U. S. 218 (1943).

[28] 318 U. S. at 226, 230-31. Of course, the paradox remains that Section 403 (g) is part of the *misbranding* provisions. As far as one can tell, any other charge of misbranding can be avoided by proper branding or labeling or repackaging. Yet a food misbranded under Section 403 (g) cannot be sold at all. Compare *Barnard v. Carey*, 60 F. Supp. 539 (DC Ohio 1945).

result is not completely unfettered. There are both substantive limitations and procedural safeguards which must be examined.[29]

The substantive safeguards derive from a combination of the words used in the authorizing language of Section 401 and the transcendental adjective "reasonable." For example, to promote the objective of "honesty and fair dealing" a standardized food is to be named—and Section 403(g) requires that such name be used on the label—but the "common or usual name" must be selected "so far as practicable."[30] As will be seen, there is no complete liberty for administrative rebaptism of foods. The regulation for identity purposes must be both a "*definition* and standard of identity," which has important bearing on how far it can depart from prevalent commercial practice. There is likewise a curious language difference in the use of "any food" in the first sentence of Section 401, and "any food or class of food" in the authorization of "optional ingredients" in the fourth sentence—which was once thought to have important bearing on how many different products might be embraced in one standard. These substantive limitations are necessarily stated in general terms but still have considerable value. But paramountly every regulation must be "reasonable."

In practice, reliance on particular statutory language and questions as to reasonableness merge in determining specific issues. Some of the more usual lines of inquiry may be reviewed. They may prove revealing to those who have not run the gamut of standard making.

B. *Common or Usual Name*

> ". . . under its common or usual name so far as practicable."

In a now famous brief, a trademark lawyer once pointed out that there is no gold in Gold Dust Flakes, no ivory in Ivory Soap, and no

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[29] See Markel, Federal Food Standards, 1 *Food Drug Cosmetic Law Quarterly* (1946) 33. The procedural safeguards of Section 701, as well as administrative practice with respect to hearings, findings, and the requirement of substantial evidence, are considered in Part III.

[30] There are also limitations of specific application, such as the requirement that in standardizing canned vegetables and canned fruits "due consideration" must be given to varietal differences; that a fill of container standard for natural foods must take account of natural shrinkage in transit and storage; and that for certain fruits only maturity and the effect of freezing can be measured.

cream in Cold Cream or in Cream of Wheat. In the formulation of food standards to date, there has been exhaustive inquiry into like questions. These arise in the initial task of determining the common or usual name of the food which is being standardized. In many instances, well-established names have been challenged as deceptive. Should Cream Style Corn be rebaptised and required forever after to be called Crushed Corn? Should Golden Corn from the Golden Bantam varietal family be rechristened Canned Yellow Corn? Must Whole Beans packed with the ends cut off and long known to the trade as Asparagus Style be relabeled as Vertical Pack; and Whole Beans not packed vertically be distinguished and for the first time called Jumble Pack or Green Beans Packed Without Arrangement? How far may the Administrator go in inventing new "common or usual" names for food or in legally effecting a change in name for established food products?

The requirement that a food must be standardized under "its common or usual name so far as practicable" was inserted in response to a curious and belated apprehension on the part of the food industry. On August 19, 1937, the House Committee agreed upon a new form of bill, and Representative Lea made the approved draft public to secure the "advantage of any construtive criticisms." At the time Section 401 did not contain this limiting phrase.[31] During informal discussions of this draft between August 1937, and January 1938, fears were expressed that in specifying a name in any standard of identity—which name would thereafter become mandatory for label use—the Administrator might select either a formidable technical name or some name other than that by which the particular food was currently known to the consumers and the trade.

At first it was thought that such fears were groundless and that further amendment was unnecessary because no administrative officer would resort to technical terminology or require strange color designations or unfamiliar descriptions for methods of pack or preparation, which

[31] See Senate 5, Seventy-fifth Congress, first session, House Report Committee Print No. 3, August 19, 1947, p. 15, and Statement By Representative Clarence F. Lea. There had been an earlier echo of the problem in Senate 2000, p. 16, Seventy-third Congress, second session, introduced on January 4, 1934, Section 11 of which prescribed that "standards of quality shall, as far as consistent with public interest, follow prevailing trade nomenclature."

were not in prevailing use. It was suggested that if any regulation so provided, it would be clearly unreasonable.[32]

As often happens, a vivid if farfetched illustration carried the day. Someone suggested that a regulation might specify that Evaporated Milk be labeled as Concentrated Bovine Lacteal Fluid! Congressional representatives, hastily appealed to, agreed that the intention was to prescribe only names in historical and current consumer and commercial use. The language "under *its* common or usual name" was therefore added to avoid any future misunderstanding. But it was likewise clear that a particular food might have more than one name widely used and known in different parts of the United States, and therefore the prescribed limitation in naming a food by "*its* common or usual name" might impose an impossible task upon the administrative officials. Accordingly, the additional phrase "so far as practicable" was added so as to authorize alternative or regional synonymous names where the evidence disclosed the necessity for them,[33] or where the record showed some recently developed name to be plainly deceptive.

In a nation occupying most of a continent, regional differences in the names of common foods are frequently encountered. What is a roll or a bun is a matter of geography. In most instances, recognition that Lima Beans are also called Butter Beans, that Tomato Puree is the same as Tomato Pulp, that Ketchup is synonymous with Catsup, that Red Sour Cherries are frequently known as Red Tart Cherries, was not difficult to secure. But in other cases, the only human disposition on the part of administrative officials to pick a new and better name for a food product

[32] The view of those who thought a further limiting amendment was unnecessary as a legal matter was based in part upon the obvious Congressional intent expressed in the section and the assumed unlikelihood of any administrative intent to exceed it, and in part upon *other references* in the bill to "common or usual name." For this phrase in substantially similar form at that time, in August 1937, appeared in two other sections: (1) In Section 403 (i), relating to unstandardized foods where the packer was required to use on the label "the common or usual name of the food, if any there be." This explicit limitation on the naming of a food by *the manufacturer* had been in the bill *since June 1933*, when it first appeared in Senate 1944, Seventy-third Congress, first session, June 6, 1933, Section 7 (f). (2) In Section 403 (g), where the label was required to bear the "common names" of optional ingredients when the regulation so required. This limitation had been in the bill since the concept of optional ingredients had been first introduced in January, 1935. (See Senate 5, Seventy-fourth Congress, first session, January 4, 1935, Section 302 (g).)

[33] As thus revised, the limiting language was unanimously added in the next draft as approved and reported to the full committee. See Senate 5, Seventy-fifth Congress, first session, House Report Committee Print No. 4, March 5, 1938, p. 16. In this form it was left unchanged and finally enacted.

has resulted in prolonged hearings and occasionally extensive briefing.[34] Frequently, argument and cross-examination centered on the use of customary adjectives, and even in retrospect it is difficult to believe that the entire weight of the administrative process was brought to bear on the question whether French Style Green Beans should instead be called Shoestring. Frequently, both sides sought to make a fortress of the dictionary. In most instances, however, these weighty questions were resolved by including the real name along with the desired regulatory nickname.

Yet that nomenclature may have serious commercial consequences is evidenced by the prolonged Cream Cheese controversy.[35] Here a difficult problem of standardization was resolved by creating two products, Cream Cheese and Neufchatel Cheese, where one product was said to have previously existed commercially. The objecting segment of the industry insisted that Neufchatel did not identify their product, that it was foreign sounding and not easy to pronounce, and that it had fallen into consumer disrepute and dislike because of an inferior product formerly marketed under that name. Even though the reviewing court found substantial evidence to support the administrative choice, it suggested that the commercial disrepute Neufchatel had suffered was not particularly significant. In another instance, the judicial rejection of the contention that a required label name, Skim Milk, was arbitrary and unreasonable because it tended to create a derogatory impression in the public mind[36] was followed by resort to Congress and resulted in the Dry Milk Solids Act of March 2, 1944.[37] While this method of dealing with standards may not readily be available and probably is not apposite to a discussion of the statutory procedure, it at least evidences the importance of the question as to what a product is to be called in the prescribed standard of identity.

Another facet of this same problem has arisen out of the enrichment program and may continue to cause difficulty. The findings underlying the regulation examined in the *Quaker Oats* case recite that the fully

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[34] In many cases, an admitted process of redubbing was involved, since no evidence of previous use of the suggested name was available. In other cases, an odd label which had come to light proved entirely too attractive.

[35] See *Columbia Cheese Co. v. McNutt*, 137 F. (2d) 576, 579 (CCA-2; 1943).

[36] *Twin City Milk Producers Ass'n v. McNutt*, 123 F. (2d) 396 (CCA-8; 1941).

[37] c. 77, 58 Stat. 108. It is interesting to note that the Congressional Committee accepted evidence that the word "skim" was a psychological barrier to better nutrition and as a name was not honest. See *CCH Food Drug Cosmetic Law Reports* ¶ 395.

enriched product had not acquired a common or usual name, and that an accurate designation would be Enriched Farina. In the light of the Supreme Court's observation that the "exercise of the administrative rule-making power necessarily looks to the future" (318 U. S. 228), it seems likely that for newly developed products, administrative selection of label names will be upheld if some witnesses, preferably consumers, can be found to endorse them.

In all likelihood, so long as the standardization program deals only with the more common staple foods, even though fabricated, this issue of proper nomenclature is not likely to become acute. But to the degree that the program extends to so-called proprietary fabricated foods, where the name of the product represents a commercial selection, backed by extensive advertising and good will, the problem may assume more formidable proportions.

C. *Inclusion and Exclusion of Ingredients—Optional Ingredients*

The task of naming a food is inseparable from that of determining its composition for identity standard purposes. Canned Peaches are packed from four varietal groups and may be prepared as peeled or unpeeled whole peaches, peeled or unpeeled halves, quarters, sliced, diced, or mixed pieces. Sometimes extra heavy syrup, heavy syrup, light syrup, or simply water is used as a packing medium; these syrups may be prepared from fruit juice or water or both; they may be made from cane and beet sugar or part dextrose. Many canned fruits and vegetables follow the same pattern. There are Eastern or Cove Oysters and Pacific Coast Oysters. An Egg may be only an egg—and a formal decision so holds—yet there are five forms of prepared eggs, i.e., Liquid Whole Eggs, Frozen Whole Eggs, Dried Whole Eggs, Liquid Egg Yolks, and Dried Egg Yolks. Examples might be multiplied throughout the field; and like variations in form of preparation, packaging, addition of particular ingredients, and combinations of ingredients are familiar in the food industry. Are these separate foods, or merely variant forms of the same food? Does the same food—with the same label name—become a different food because differently prepared or packaged? Is the addition of a single ingredient, e.g., color, preservative, emulsifier, or enriching vitamin, to be permitted as an "optional ingredient"—and merged in the prescribed name—or to be forbidden because it makes a legally different food?

Whether the standard of identity covers a single food, e.g., Liquid Whole Eggs, or an entire class of foods, e.g., Canned Vegetables, is for many purposes academic, and largely a question of administrative convenience. Any number of separate foods, for example, may be considered in one hearing.[38] But in particular cases, the structure of the standard—and whether it comprehends one product or a whole group of products—may be important. The separation of Farina and Enriched Farina into two separate foods, with mutually exclusive multiple ingredients, had important consequences. The structure of the standard may control the reasonableness of excluding a particular ingredient. It may affect the validity of applying a contested measure of identity to different things which appear superficially similar. Or it may, as will be seen, bear on the question whether the same food can be treated as two different foods because there are two ways of manufacturing it. Consideration of both theory and administrative practice on these issues is worthwhile.

Analytically, the preferable approach is by way of the statutory text. After authorizing a standard of identity for "any food," Section 401 provides that

"In prescribing a definition and standard of identity for any food *or class of food* in which optional ingredients are permitted, the Administrator shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label."[39]

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[38] For example, all flour and related wheat products were heard together, eventuating in 16 separate standards. In 1939, a hearing to consider a standard for Mixed Vegetables resulted eventually in a single standard (or separate standards?) for 43 vegetables, and no standard for mixtures.

[39] This authorization was a late addition to the bill. The necessity for standards of identity, the corollary requirements of Section 403 (g), and the importance of requiring ingredient disclosure for foods which had previously been exempted under the "distinctive name" provision of the old law, were extensively canvassed from the beginning of Congressional consideration. See, e. g., Hearings on Senate 1944, Senate Committee on Commerce, Seventy-third Congress, December 7 and 8, 1933, p. 35 *et seq.* But the concept of an "optional ingredient" in a definition and standard of identity first appeared in January, 1935, after two years' Congressional consideration of new food and drug legislation. Senate 5, introduced by Senator Copeland on January 4, 1935, Section 302 (g), provided a somewhat indirect authorization for the inclusion of optional ingredients in any standard of identity. See Senate 5, Seventy-fourth Congress, first session, Section 302 (g), pp. 6-7. Where a definition and standard of identity had been prescribed, this section required that the food conform to, and that its label bear the name prescribed in, the standard *"and if so required* by such regulations when such definition and standard permits optional ingredients other than spices, flavors, and coloring, the common names of such optional ingredients as are present in such food." This rather backhanded way of authorizing the inclusion of optional ingredients in a standard was left unchanged until 1937. At that time the Senate Committee replaced the word "and" with the word "or" (see Senate 5, Seventy-fifth Congress, first session, Senate Report No. 91, February 15, 1937, p. 22), but when the bill reached the House, the House Committee immediately restored the "and" (Senate 5,

This language must be read together with the last phrase of Section 403(g), which specifies that the label of any standardized food shall bear

"insofar as may be required . . . the common names of optional ingredients present in such food."

Taken together, these two sections clearly authorize the inclusion in a single standard of two or more food products containing the same *basic* ingredients but differing in the presence of one or more optional ingredients. The controlling phrases appear to be

"class of food"—class meaning to have the same basic ingredients and general identity;

"optional ingredients"—substances not essential to identity or not always present, but which in ordinary commercial practice are sometimes present and sometimes absent; and

"permitted"—which means that, though optional, such ingredients may be included in the standard, with or without separate label identification as the Administrator determines.

Of course, the Administrator may treat each food product within the class [40] as a separate food and establish separate standards after separate hearings. But the broader authority for considering in one standard an entire group of products—having common ingredients and occasional additional ingredients—was necessary for at least two reasons: first, it afforded a desirable administrative shortcut under an otherwise

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Committee Print No. 1, Seventy-fifth Congress, first session, March 10, 1937, p. 23). After further consideration, the House Committee, on July 23, 1937, rewrote the entire provision to read as it appears in the Act. (See *id.*, Committee Print No. 2, p. 21.)

Up to this time, apparently no one had thought that specific authorization in Section 401 for the inclusion of optional ingredients was necessary. But when the House Committee revised the language of Section 403 (g) in July, 1937, it also added the fourth sentence of Section 401. It is unfortunate that no comment was made at the time or in subsequent legislative consideration which throws any light on why these changes in language and additions were made. The meaning of these two sections with respect to optional ingredients must be derived solely from their context.

[40] The use of the slightly different phrases "any food" in the first sentence of Section 401 and "any food *or class of food*" in the fourth sentence, may have been a legislative oversight. For up to July 23, 1937, the various bills had uniformly authorized standards "for any food." On that date, the House Committee, when it added the authority to include optional ingredients in "any class of food" (see Note 39, *supra*), also changed the first sentence to cover "any food *or class of food.*" See Senate 5, Committee Print No. 2, Seventy-fifth Congress, first session, p. 17. On March 5, 1938,—after Mr. Lea had circulated the House draft for comment—the phrase "under its common or usual name so far as practicable" was added to the first sentence, and the words "or class of food" deleted. See *id.*, Committee Print No. 4, March 5, 1938, p. 16. The fourth sentence was not changed. The deletion in the first sentence may have been inadvertent since the same phrase was retained in the fourth; and when Congress conferred authority to include optional ingredients, it may have meant that the Secretary could deal with "any class of food" in a single standard. Similarly, the term "a food" in Section 403 (g) may be read to include "any class of food" embraced in a single standard of identity.

rigid and possibly cumbersome procedure; and, second and of paramount importance, it permitted the appropriation of a *single name* for the group or class without encountering difficulties under Section 403(g) or 403(c). For example, cream cheese, with or without gum, could still be Cream Cheese, and no question would arise as what cream cheese with gum "purports to be" under Section 403(g) or whether it is or is not an "imitation" under Section 403(c). Canned Peaches with all variations of syrup or form of peaches can be by regulation the same product under that name.

Logical as this seemed, early administrative practice was somewhat confusing. Instead of building a standard around basic ingredients and optional ingredients, a group of foods was thrown together and each separate food called an "optional form of ingredient." Sometimes this was done, as in the case of Canned Peas, to get away from difficulties under the McNary-Mapes Amendment [41] which, it was possibly thought, might continue under the new Act. Another explanation may be that it permitted—many think improperly—control of manufacturing processes under the guise of standardization. (This point will be separately treated.) Or these may have been only normal incidents in the development of the standardization technique under the statute. More recently, the procedure seems to be to consider related foods, e.g., all cocoa products, all breads, all types of corn meal, all macaroni and noodle products, in one proceeding; but to attempt to segregate each food having *common basic ingredients* in a separate standard with an exclusively appropriated name, e.g., Bread and Rolls, Milk Bread and Rolls; and to deal with optional ingredients in relation to each standardized product.[42]

But the process is still flexible and in an evolutionary state. The administrative Linnaeus is still unborn. Overlapping and apparent inconsistencies are inevitable as are adjectival expedients. Bread alone may mean white bread; add the adjective Milk and you have a separate product, Milk Bread (e.g., Cocoa, Breakfast Cocoa, Low-Fat Cocoa,

[41] This amendment to the 1906 Act and the difficulties which followed from its use of the phrase "generic product" is examined in detail in the discussion of standards of quality in Part II.

[42] Mr. Callaway comments: "Section 401 . . . contemplates definitions and standards of identity for single foods and for classes of food. Distinction between these types of definitions and standards has introduced a number of problems. It has been our theory that definitions and standards for individual foods should be specific and mutually exclusive. This theory, although apparently simple and easily followed, has led to difficulties on many occasions." Callaway, Current Problems in Formulating Food Standards, 2 *Food Drug Cosmetic Law Quarterly* (1947) 127-28.

etc.). The genus covered by the single standard may be Green Beans, but for label purposes each species will have to be identified as Whole Green Beans, Cut Green Beans, Short Cut Green Beans, etc., which in effect yields the same result as having separate standards.

For practical purposes, the problem may be divided into two parts, each of which may be separately examined: (1) How many separate foods and separate names (wholly different or compound forms) should there be for a group of related products? (2) In each, what optional ingredients should be recognized and which should be specifically shown on the label of the standardized food?

1. In determining the first question, past experience offers a few guides as to what will be considered necessary "to promote honesty and fair dealing in the interest of consumers." Any significant *physical* difference in composition or appearance will mean separate standards and label names. Any difference in form of preparation believed to be of importance to the consumer will be recognized. The difference may be functional, as in the obvious cases of whole fruits for salad use or slices for pies, the various lengths of asparagus, or whipping and coffee cream, self-rising and plain flour. Or it may be in flavor, e.g., as in the difference between bitter and sweet chocolate. It can even be what some have called an "optical condiment," as in the case of colored cherries in Fruit Cocktail. Inclusion of an ingredient may be recognized with minimum and maximum amounts where concentration changes identity, e.g., Tomato Puree vs. Tomato Paste; Canned Fruits vs. Fruit Preserves. Another invariable ground for identity fission is the relative amount of some important (and usually costly) ingredient, e.g., fat content in cocoa products, butter fat in cream and in cheese, syrup density in canned fruits, moisture content in many products, etc. Enrichment or fortification probably will mean a separate standard (and this subject raises enough complications to warrant separate and extended consideration by some qualified person). Lastly, there are some factors of peculiar significance, such as adding alcoholic beverages. Brandied Cherries or Peaches With Rum are properly considered different from the ordinary canned products.[43]

[43] Brandy is an "optional ingredient" in several canned fruit standards; but when rum is added, separate standards are provided. While the difference means largely a difference in prominence in labeling, since both must be shown, it may be commercially important. This variation in treatment, however, may be attributable to a developing policy as to how to treat this type of product differentiation.

In these determinations, two interesting questions sometimes emerge. The first is that the test of promoting "honesty and fair dealing" for consumers is an economic measure of what consumers deem important. It is *not* what expert social or medical data might reveal should be important, but what the evidence shows the consumer thinks is important. Two products may be either nutritionally equal or widely different in nutritional value. (Here one must avoid the risks in venturing examples.) Yet only to the extent that consumers evidence interest in knowing, could it properly be argued that the statutory test is applicable. Of course, it is assumed that no one wants to be defrauded, but the differences dealt with in standards of identity are not necessarily of the degree amounting to economic fraud. This point assumes greater importance in standards of quality but is also often involved in identity standards.

Because of it, the question of what is adequate evidence of consumer interest, elsewhere discussed, becomes essential. And it would appear that some of the confusion about the *Quaker Oats* decision turns on the same point. It was not because the Administrator had power to ordain the American diet that his order stood, but because he found, the Court said properly, that consumers were interested in enrichment and likely to be confused.

The other question is the degree to which existing commercial practice is relevant. It has been seen that in selecting a "common or usual name" for existing foods, what they have been historically called should have great weight. But how far this argument applies in determining a standard of identity is difficult to appraise. In the *Cream Cheese* case, commercial practice by a fair segment of the industry in calling a lower-fat higher-moisture product by that name fell in the face of a finding suggesting fraud. But this rested in turn on historical evidence as to the trade name for the "traditional" product. In some instances, commercial practice is so divergent as both to reinforce the need for a standard and to permit the widest administrative choice in definition. In others, there has been evidenced an apparent administrative effort to raise to a new level what most manufacturers had been doing.[44]

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[44] "If standards are to fulfill their purpose, they must make it possible to bring about improvements. One of the early standards of identity adopted was that for evaporated milk. It required slightly more milk fat in this food than was the accepted practice. It may be argued that such a standard would have the effect of driving from the market an old established food, meaning the evaporated milk with the milk fat content previously recognized. No such statements, however, were made by the

It is here that attention turns to the precise wording of Section 401. What is authorized is "a *definition* and standard of identity." To define, one must examine what is being done. The composition of a food may be fairly well established and followed by most manufacturers. Just how far the Administrator may go in changing commercial practice is often the submerged reef in a particular proceeding to formulate a standard.[45] Where the issue is acute, it is essential that the Administrator be given the advantage of a record containing adequate evidence of prevalent commercial practice and the effect of proposed changes.

2. Optional ingredients assume importance because failure to recognize them means that they cannot be used. This is important to the manufacturer who has developed their use and the supplier who has perhaps developed facilities to make them.[46] Relevant factors in the administrative decision have to some extent been revealed in practice.

The first is that the optional ingredient must be harmless in itself. If any question as to deleterious character is raised, exclusion seems clearly warranted.

Extent of use is very significant and necessarily related to the general question of previous commercial practice. The extent to which the particular ingredient is optionally used in the total volume of the food sold under the appropriated name should have an important bearing on the reasonableness of excluding it. This is largely a question of degree but, because of the consequences of exclusion, it is usually resolved in favor of the ingredient.

The function of the ingredient is likewise relevant. Where its addition reflects improved methods of manufacture, or changes in the mode or manner of consumer use of the product, or scientific illumination by research into the character or composition of the food, it should be permitted.[47] Intelligent administration should not limit a standard of

evaporated milk industry, and the requirements of the new standard were promptly met." Callaway, Current Problems in Formulating Food Standards, 2 *Food Drug Cosmetic Law Quarterly* (1947) 137.

[45] Usually the question is argued in terms of "substantial evidence." If several canners testify that trade understanding of Tomato Puree is a product of X specific gravity, and several Government witnesses say it is, *or should be*, X + Y, is this substantial evidence on which to fix the level at X + Y?

[46] Compare *Staley Mfgr. Co. v. Secretary*, 120 F. (2d) 258 (CCA-7; 1941); *American Lecithin Co. v. McNutt*, 155 F. (2d) 784 (CCA-2; 1946) [*CCH Food Drug Cosmetic Law Reports* ¶ 7011].

[47] Thus the use of various calcium salts to firm tomatoes has been permitted by two amendments to the canned tomato standard, and two amendments made to the pea standard to permit the use of magnesium salts.

identity to crude recipes developed under primitive conditions but should reflect the farthest advance of food manufacturing techniques. Yet an ingredient which makes for manufacturing economies often runs into trouble as shown by the consideration of the use of gum in cream cheese and benzoate in catsup. An added optional ingredient may make a better product, or the same product at a lesser cost. The latter case always raises the suspicion that savings in costs is a paraphrase for cheapening of the product.

Finally, there is considerable doubt as to how far an optional ingredient may be recognized where it actually changes identity. Ingredients have been excluded, on the theory that the flavor of the product is an essential part of its identity, where their addition would drastically modify flavor. Yet spices have been invariably recognized and these certainly change flavor in many instances.[48] The only apparent test, though never precisely articulated, is whether the change in flavor which an optional ingredient will make is one which would be readily identifiable to the consumer by label statement of the ingredient (e.g., Seasoned With Mint, or Garlic, or Horseradish).

This points to the remaining question whether an optional ingredient whose use is permitted should be designated on the label. Here the same tests are generally applicable. If the ingredient merely facilitates manufacture, e.g., yeast nutrients in bread, label disclosure may not be required. Or an ingredient not unexpected in the product need not be labeled, as illustrated by salt in canned vegetables or by the controversy whether sugar (sucrose) in canned fruit should be labeled as "cane sugar" and "beet sugar." But the trend seems to be in the direction of complete label disclosure and to a virtual elimination of any distinction between the requirements of Sections 401 plus 403(g)(2) and Section 403(i). Those believing in fully informative labeling have encouraged this trend.

D. *Control of Methods of Manufacture*

In many proceedings to establish a standard of identity for a food or class of food, there lurks the question whether by use of Section 401 the Administrator may control or modify methods of manufacture. The

[48] Where spices are permitted as optional ingredients, Section 403 (g) does not require them to be separately labeled. In other words, they are recognized as proper components of a food which the consumer recognizes under that name.

issue arises in two ways: (1) The standard of identity may describe the product in terms of how it is made and require different labeling according to method of manufacture; or (2) the specifications may be met only by the use of particular machinery not in general use or by methods not usually practiced. Discussion of each possibility is warranted.

1. *Definition in Terms of Method of Manufacture.* At the outset, it must be recognized that different methods of manufacture may result in identity differences, and that frequently the easiest way to describe the product is to recite its method of manufacture. But this is true only where the product can be made only in one way or, conversely, where a difference in method makes some detectable difference in what is produced.

Trouble arises where, as sometimes happens, the same product can be made in two ways and the result is indistinguishable. If the Administrator concludes that the consumer is entitled to know of the difference in manufacture, may he lawfully require label differentiation either in the same or two different standards of identity? The answer, experience indicates, turns on what Section 401 means and on how far the practical enforceability of a standard is relevant to its reasonableness. Enforceability may likewise bear on whether "honesty and fair dealing" will be achieved where an honest manufacturer might practically be left at the mercy of an unscrupulous one.

These questions may best be explored by a case history—not to reopen an issue which is controversial within the industry itself—but to use it as an illustration. In a canning operation employed in one state, raw tomatoes are segregated into those used for canning as whole tomatoes and those used for juice and puree. In preparing the whole tomatoes, the skins and cores are cut away with some tomato flesh, and the fruit also bleeds juice. These cores and skins and drained juice are put through a machine called a cyclone, to remove the skins and seeds and hard fiber, leaving the juice and flesh. This is concentrated as puree. In the making of tomato juice, only part of the juice is extracted, and the remaining flesh and juice in the tomato similarly treated in the cyclone and concentrated to yield puree. Or whole, usually pale colored, tomatoes may be similarly cycloned and concentrated to yield puree. There was considerable evidence that the resulting products from all three methods were indistinguishable, that each in the end contained juice and sus-

pended flesh of tomatoes, and that the resulting products varied no more than variations in the product made from different batches of whole tomatoes. Significantly, there never was any finding to the contrary.

Despite extensive testimony and elaborate briefing, the final standard described three supposedly different types of raw material (i.e., tomato cyclone pulp made by three variant ways of abstracting tomato flesh and juice) as "optional ingredients," and required that *except for whole tomatoes* "the label shall declare the raw material used" respectively as Made From Residual Tomato Material From Canning or Made From Residual Tomato Material From Partial Extraction Of Juice.[49] The processors concerned first contended that since the end products were indistinguishable and chemically and botanically were each flesh and juice from tomatoes, and that since there was no showing of any difference in cost of manufacture (and no question of adulteration),[50] this commercially derogatory label requirement could not be related to "honesty and fair dealing in the interest of consumers."

Their first point was that standard classification on the basis of method of manufacture was unwarranted under the Act. It was argued that a product made from tomato juice and flesh could not be made into two products by calling the cyclone juice resulting from different ways of dividing a tomato different "optional ingredients." An ingredient which was the principal constituent could not be made "optional" by administrative fiat; but, urged the brief, an optional ingredient is "one which in ordinary commercial practice, is sometimes present and sometimes absent." It was further argued that Section 403(g) required that the "optional ingredient" be "present in such food" which meant that some detectable difference in the finished product must be found.[51]

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[49] If these two types of cyclone juice are combined in manufacture, the label requirement is "Made From Residual Tomato Material From Canning And From Partial Extraction Of Juice."

[50] In the standardization of tomato juice, the evidence revealed that one manufacturing process, which contributed largely to the total production, involved the application of steam to crushed tomatoes and subsequent evaporation to remove the calculated amount of added water which had condensed. There was considerable discussion as to whether this was "dilution" or "adulteration." The regulation finally issued identified the product according to method of manufacture and specified that, "In the extraction . . . heat may be applied by any method which does not add water thereto." The findings made clear the administrative view that the process in question could remove "only part of the water which was added as steam condensate." As a consequence, it is reported that this manufacturing method was abandoned.

[51] Compare the findings on the use of gum in cheese where a similar situation existed, but no distinction according to method of manufacture was made in the final regulation other than to require labeling of Added Gum.

The strongest attack centered on unenforceability. Evidence on this point was refused admission at the hearing. Nevertheless, it was urged that reasonableness is not only a criterion of economic burden but that *an unenforceable standard* can never be reasonable because the honest manufacturer suffers competition from the unscrupulous. Of course, identity standards based on methods of manufacture can be enforced by factory inspection, but all inquiry into the possibility of this method of enforcement was foreclosed at the hearing.

This issue drives deeply into the basic purpose of standards.[52] It is doubtful whether anyone will seriously contend that the Act contemplates continuous factory inspection in the food industry or that present budget or personnel would permit it.[53] There must be a manifest probability of enforcement in what is prescribed. For if the result of a standard may be to permit the consumers to be defrauded by violators, dishonesty and unfair dealing may be promoted.

2. *Methods of manufacture* may likewise be affected by what the standard prescribes. For example, the limits specified for Cuts and Short Cuts on some canned vegetables raise the question whether the required segregations can be realized with existing machinery; and in the case of quality standards the issue is always presented as to what the labor cost will be or the mechanical feasibility of achieving a particular level of workmanship. Rarely if ever is the standard based on the use of a machine or method that is not employed by somebody. The difficulty usually concerns machines or methods employed by a minority (whose methods are termed in record "good manufacturing processes"); and the effect of the standard may be to require their adoption by all—financial ability, cost of operation, or technical skill notwithstanding.

It is also only fair to say that this result is usually inadvertent and the result of an incomplete record. Usually, the more advanced manufacturer participates in the hearing. Evidence of what he does may be

[52] Occasionally, what is done in manufacturing may not be clear. One form of optional ingredient for Canned Peaches is Mixed Pieces of Irregular Sizes and Shapes. Another form is Halves. Where Halves are excessively trimmed, it will be seen that the product becomes Substandard. The subtle difference between the two concepts has been the subject of litigation. Probably, the only way to determine this issue—whether the canner is striving to pack Mixed Pieces or Halves—would be by close factory supervision.

[53] This same problem arises in a less apparent form in standards of fill of container which are considered in Part III. There examination will be made of the legality of a standard which can be enforced only by continuous factory inspection.

the only evidence. In large measure, responsibility for any resulting hardship lies with those who fail to appear. But assuming an adequate record, the legal issue of how far a standard of identity can result in changing what a substantial part of an industry does in its commercial practice remains to be finally determined.

E. *Revision of Identity Standards*

Despite the apprehensions voiced, the record to date discloses little basis for worry that the promulgation of standards of identity will freeze developments in the food industry. It is true that articles incorporating newly discovered ingredients, representing departures from the standard, may not lawfully be shipped interstate. Yet few difficulties are in practice encountered in establishing the worth of a change by intrastate shipment where state law permits. Amendment of the Act to permit administrative authorization of experimental production, probably upon application, would not be objectionable.

It is true that standardization results in the disclosure of the new methods or ingredients at a public hearing. But patent protection is still available, and in several instances patented combinations of ingredients or a patented process have been recognized in a standard. Where such protection is not available, disclosure is part of the price which must be paid for the standardization program which Congress has determined is in the public interest.

The Administration's record cannot be challenged. The Canned Pea standard was twice readily amended to recognize new processes; the Canned Tomato standard twice amended to permit additional ingredients; the standards for both Asparagus and Cherries were amended to permit additional packing media; the Flour standards have been amended, with respect to enrichment; and an additional standard promulgated to permit specified uses of corn syrup in condensed milk.[54] Except in two cases resting upon particular facts, one of which is now in litigation,

[54] While the Act requires that application for amendment be by a "substantial portion" of an industry, the Administration has in fact entertained and called a hearing on the application of a single company. This is probably now required by Section 4 (d) of the Administrative Procedure Act. Compare *Cook Chocolate Co. v. Miller*, 72 F. Supp. 573 (DC D. C. 1947) [*CCH Food Drug Cosmetic Law Reports* ¶ 7056].

there appear to have been no instances where a clearly merited application to reopen a standard has been denied. And there is a ready disposition to re-examine any requirements which turn out in practice to be unworkable.[55]

II

> ". . . a reasonable standard of quality . . ."
>
> "Eight women sat around a table in the Department of Agriculture Building yesterday, their attitude very scientific. The object of their attention was an unsuspecting can of peas.
>
> "Finally a voice of authority posed two questions which projected the eight women into channels of deep thought.
>
> "If you purchased this article labeled simply as 'peas' would you be satisfied with it for service at a usual meal in your home? If not, in what respects do you regard this can of peas as unsatisfactory?" *Washington Star*, November 8, 1930.

This scene witnessed the beginning of an informal hearing on the first standard of quality to be promulgated under a Federal Food and Drug law. Culminating two years' effort, the canning industry had secured the enactment on July 8, 1930, of the McNary-Mapes Amendment.[56] This provision became the progenitor of the authority in Section 401 of the 1938 Act for the promulgation of *a* reasonable standard of quality for any food. It is therefore not surprising to find that all of

[55] In this connection, it should be noted that Section 701 (e) provides that the Administrator on application by an industry "shall" hold a hearing on any application to amend or repeal a regulation issued under Section 401. Mandamus might be available for any unreasonable refusal (compare Section 10 (e) (A) of the Administrative Procedure Act).

[56] See Act of July 8, 1930, c. 874, 46 Stat. 1019, House of Representatives 730, Seventy-first Congress, second session. Three efforts to pass this bill on the consent calendar in March and April failed. 72 *Congressional Record* 4719, 5447, 6631. The 1930 Senate debate foreshadowed the later agitation for a complete system of vertical quality grading for foods. See Senate 1135, 72 *Congressional Record* 10495, June 11, 1930. As previously noted, the phrase "to promote honesty and fair dealing in the interest of consumers" originated in substantially the same form in the McNary-Mapes Amendment. The concept of a public hearing in Section 701 likewise originated in a rejected Senate amendment in 1930. See 72 *Congressional Record* 10495, June 11, 1930. The McNary-Mapes Amendment was repealed by Section 902 of the 1938 statute, along with the remainder of the Food and Drug Act of June 30, 1906.

the seven standards of quality thus far issued under the 1938 Act are for canned foods. The McNary-Mapes Amendment had authorized for each canned food a single or minimum standard of quality. In general, Section 401 extended this authority to embrace all foods. In developing quality standards, the Food and Drug Administration has in large measure followed the pattern evolved under the canning industry amendment to the old law.

At the outset, it is important to point out what Section 401 does and does not authorize in the way of quality standards, as well as to indicate the relationship between a standard of identity and a standard of quality. The section authorizes the establishment by regulation of "a" reasonable standard of quality for any food. This relatively simple phrase is the result of a prolonged legislative battle over the question whether Congress should grant administrative power to establish what would in effect be a government grading system for all food products.[57] The original so-called Tugwell Bill, Senate 1944, introduced in June, 1933, provided broadly for "standards of quality." This would have permitted the establishment of the system variously known as vertical grading; A, B, C, and D grading; or any other required label designation in a government grading system segregating Poor, Good, Fair, and Best. Vigorous opposition resulted in the change in Senate 2800, the 1934 bill, to a more limited authority to promulgate "one objectively determinable minimum standard of quality" so as to reflect the former McNary-Mapes Amendment practice. In the 1934 Senate Report, this language was changed to its present form.[58]

Interpreted in the light of its clear legislative history, this part of Section 401 authorizes the establishment of a single or minimum standard of quality separating a particular food into Substandard and Standard or better. By Section 403(h)(1), this segregation is carried through to the label of the product to require label differentiation only for the

[57] For a brief summary, see Cavers, The Food, Drug, And Cosmetic Act Of 1938: Its Legislative History And Its Substantive Provisions, VI *Law and Contemporary Problems* (1939) 25-26.

[58] The Senate Report made the legislative intent clear by stating that the authority to issue quality standards for all foods was "in effect an extension of the present law, which, by the terms of the McNary-Mapes amendment, authorizes the establishment of one standard of quality." See Senate Report No. 493, Seventy-third Congress, second session, March 15, 1934, p. 11. Those interested in conveniently tracing this point in the legislative record may do so in Dunn, *Federal Food, Drug, and Cosmetic Act* (1938) pp. 43, 70, 78, 95, 120, 174, and 194.

substandard product. Any departure from the standard of quality alone thus does not bar sale of the product but simply results in additional labeling requirements.

Logically, a standard of quality can operate only within the confines of a standard of identity. The product is first measured to determine whether it conforms to the standard of identity—if it does not and it either purports to be or is represented as the standardized food, it cannot be lawfully sold. The standard of quality begins to operate only when the food conforms to the standard of identity, or as it has sometimes been put, "a standard of identity encompasses a standard of quality." As a practical matter, this means that no standard of quality can be promulgated unless there already has been or there is simultaneously issued a standard of identity. One must first know what he has before he can determine whether it is an acceptable or inferior sample.

The simplicity of the distinction is somewhat illusory. One of the most difficult questions in standard making is to determine whether a particular characteristic differentiating one food product from another should be considered a factor of identity or a factor of quality. This inquiry is far from academic. In most instances the two products are enough alike that calling the differentiating characteristic an identity factor would forbid the sale of one of them. Designation as a quality factor would mean that both could be sold but that one would have to be additionally labeled as Substandard.

Previous experience under the McNary-Mapes Amendment had shown that it was undesirable to attempt to control differences in identity by calling them differences in quality. That statute had, probably to avoid vertical grading, specified that the term "class of canned food" for which a standard of quality might be prescribed was limited "to a generic product . . . and does not mean a grade, variety or species of generic product." In 1932, a standard of quality was promulgated for Canned Peas to include both canned immature peas freshly harvested and canned soaked, dried peas. Maturity was made a factor of quality rather than of identity; and the soaked, dried product was denominated Substandard. An injunction against enforcement of this regulation was

sustained on appeal [59] on the ground that soaked, dried peas were a "separate class," i.e., had a separate identity; and could not be regarded merely as an inferior grade of canned immature peas. Since the language of the McNary-Mapes Amendment was thought to preclude two separate standards for the two types of peas, the desired distinctive labeling could not be required.

Legislative history makes it clear that the lesson of *Nolan v. Morgan* led to the elimination of the troublesome phrase "generic product" in the present law. When Canned Peas were standardized under the 1938 Act, the distinction between the immature and the dried soaked product was recognized as a factor of identity rather than quality. The soaked dried peas were made a separate food under the name Dried Peas and the immature product standardized as Peas. Thus dried, soaked peas can no longer be canned and sold simply as Peas because the maturity difference is now an identity factor. If, however, the difference had still been considered a quality factor, the dried soaked product might still have been sold as Peas but would have borne the substandard legend.[60]

Trade usage is not controlling in deciding what is a factor of identity and what is a measure of quality. The density of the syrup in which canned fruits are packed has long been regarded by the trade as a factor of quality.[61] Nevertheless, syrup density is considered by the Food and Drug Administration and appears in its standards as a factor of identity. Further complication exists where a particular differentiation may be *both* a factor of quality and a factor of identity. Whether Canned Cherries are pitted or not is a question of identity—e.g., Pitted Dark Sweet Cherries as against (unpitted) Dark Sweet Cherries—but the presence of too many pits in Pitted Canned Cherries is a quality factor. The supposed difference between Cut Green Beans and Short Cut Green Beans is a matter of identity. Yet the quality

[59] *Nolan v. Morgan*, 69 F. (2d) 471 (CCA-7; 1934). For a full discussion of the administrative background of the regulation and the details of the litigation, see Fuchs, The Formulation And Review Of Regulations Under The Food, Drug, And Cosmetic Act, VI *Law and Contemporary Problems* (1939) 56-62.

[60] Prior to 1932, the dried pea product, it is true, had to be labeled "Prepared from Dried Peas," but the difference between the substandard legend required in 1932—"Below U. S. Standard. Low Quality But Not Illegal. Soaked Dried Peas"—and the currently required labeling merely as Dried Peas is quite important. As will be seen, the substandard legend is referred to in the trade as the "crepe label."

[61] This is recognized in commercial standards which make the commercial quality grade of the particular canned fruit dependent upon the density of the syrup. See *Specifications For California Canned Fruits*, Canners League of California.

standard for Cut Green Beans provides that more than a specified number of short pieces will make the product substandard. There is no corresponding tolerance for long pieces in either standard of identity. Thus a can of beans may be either standard Cut Beans (if there are not too many short pieces); or Substandard Cut Beans (if there are more than the permitted tolerance of short pieces); or an entirely different product, Short Cut Beans (if there are a predominant number of short pieces).[62]

A further illustration of the problem may be found in the Cream Cheese proceeding. Here the differentiation according to fat and moisture content led to the standardization of two separate foods under two different names, Cream Cheese and Neufchatel Cheese. Conceivably, the Administrator might have included the latter product within the standard of identity for Cream Cheese but made the lower-fat-higher-moisture distinction the basis for a standard of quality. The result might have been a differentiation on the basis of quality between Cream Cheese and Substandard Cream Cheese. It is not at all unlikely that one of the reasons which militated against this decision (apart from technical problems with respect to notice), was the judgment as to the relative commercial consequences of requiring a wholly different name as against requiring a substandard label legend.

What must appear in a substandard label legend is a matter of administrative discretion—subject to the requirement that it be reasonable. All that Section 403(h)(1) requires is a statement that the product falls below the standard of quality set forth "in such manner and form as such regulations specify." In the canning industry, at least in the days of the McNary-Mapes Amendment, the required substandard legend was referred to as a "crepe label." The theory was that the substandard product should be so labeled as always to set it apart from the standard or better product. "The purpose of the canners' bill," Dr. Dunbar explained in 1930, "is to authorize the formulation of such legal standards as will insure a product sold to be of at least a standard degree of excellence, while an article which has reached such a degree of in-

[62] This is a simplified statement of the provisions of these regulations, but it serves to illustrate the relative effect of selecting a particular characteristic for both identity and quality standard purposes.

feriority as to offend the purchaser, *even though that article be perfectly wholesome and nutritious*, will be definitely labeled to show that it is substandard, and therefore will not be bought at the ordinary price."[63]

This statement may serve as a twofold text—to demonstrate the kind of differences in products which have been administratively determined to warrant the distinction between Standard and Substandard, and to review what makes the substandard legend so derogatory as to have earned the designation "crepe label."

In general, differences in *workmanship* constitute quality factors. This usually lies in sorting table procedure. In the case of fruits, the selection of uniform sizes is considered highly important; minimum weights for halves and quarters are prescribed; or for whole fruits, the weight of the largest unit cannot be more than twice the weight of the smallest unit. In fruit mixtures, not more than a given percentage of certain fruits may be cracked or crushed beyond normal shape. Stems cannot be left attached to fruits. The sorting out of blemished fruits—those containing scab, hail injury, discoloration, scar tissue, or other abnormality—may mark the line between standard and substandard. Similar factors reflecting the difference between some manufacturing practices and other poorer ones are regularly included in a standard of quality.[64]

Occasionally a factor which in gross form may change identity will in lesser degree simply mark the line between Standard and Substandard. Maturity of the raw material canned is basically the difference between the two identity standards for Peas and Dried Peas. But differences in maturity in a lesser degree also mark the difference between Standard and Substandard Peas.[65] As another example of undesirable maturity, the presence of tough strings in Green Beans is a quality factor. In some

[63] See National Canners Association *Information Letter* No. 381, November 15, 1930, p. 2233. The italics have been supplied.

[64] The same problem exists here with respect to how far a standard may depart from prevalent commercial practices. See the preceding discussion of this point in the consideration of standards of identity, *supra*, pp. 552-53.

[65] Indeed, it was on this issue that the single court case in which a standard of quality was involved resulted in the standard being declared invalid as applied in that instance. *United States v. Lord-Mott Co.*, 57 F. Supp. 128 (DC Md. 1944). There a different measure of maturity had been prescribed for different varieties of peas. It was held that the level prescribed for one variety was unreasonable. The importance of varietal differences in determining quality standards underlies the provision in Section 401 that in "the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable."

instances, a difficulty which in gross degree would perhaps render a product adulterated may in lesser degree make it merely substandard. Unsound food may result in adulteration on the ground that the product is "unfit for food" (Section 402(a)(3)). Yet minor imperfections, such as rust or insect injury or the presence of extraneous vegetable matter, may indicate the line between standard and substandard.[66]

Artificial coloring requires separate mention. Ordinarily, artificial color is an identity factor. It is so treated for cherries in fruit cocktail. Misuse of artificial color to conceal inferiority, or to make a product appear better than it is, falls within Section 402(b) and is condemned as adulteration. Yet under the McNary-Mapes Amendment regulations, artificially colored peas had been ruled substandard and had to carry the crepe label. In the standardization proceedings under the 1938 Act, however, it was urged that artificial color in peas was properly an identity factor because many high quality peas were so colored. This argument was rejected. The Administrator found that "color is one of the factors of judging the value and quality of canned peas." The regulation required that the colored product be labeled "Below Standard In Quality—Artificially Colored" irrespective of the quality of the product measured by other factors.[67] Necessarily, the use of color to dress up an inferior product was not involved. Nor was substantial discoloration of the raw product, since concealment of this defect would equally be adulteration. The ruling was equivalent to an administrative determination that because an optional ingredient might be misused in unlawful fashion, wherever it was used it always denoted poor quality. Perhaps this adds up to employing a quality standard to discourage use of an ingredient which is disliked or feared where the evidence does not warrant complete exclusion. The technique of requiring a Substandard label is obviously

[66] As a hedge, the General Regulations for all food standards (Section 10.0) state that no provision of any standard affects the application of other provisions of the Act. As an example, it is stated that "all regulations under section 401 contemplate that the food and all articles used as components or ingredients thereof shall be clean, sound and fit for food . . ." Somewhere between the level of rust or insect injury or extraneous vegetable matter which makes a product Substandard (but still saleable) and the amount which constitutes adulteration, there undoubtedly exists an unspecified administrative tolerance.

[67] Presumably, one may do what he can to avoid the effect of a crepe label. It was reported that for a time at least one packer used the required Substandard label and added to it substantially the following truthful statement: "These peas are the finest Fancy quality packed by us. The statement that they are Below Standard solely because artificially colored is required by a Federal Regulation."

more of a deterrent than recognizing artificial color as an identity factor and authorizing the sale of Artificially Colored Peas under a separate, distinctive name.

To summarize what are quality factors, any difference affecting the appearance or use of the food may be selected by the Administrator. The test appears to be whether, in the light of the purpose for which the particular product is purchased, the difference would be deemed important by the consumer. If the imperfection would lead her to consider the product not acceptable, it may be marked out as a factor to be measured in the standard of quality. To a considerable degree, trade practice in classifying products as above or below the standard line is relevant to reasonableness. Yet basically the inquiry leads, as do most under Section 401, to the ultimate question as to what constitutes substantial evidence of consumer ideas of relative economic value. As earlier noted, the emphasis must be on prevalent consumer concepts—not on what she *should* consider quality factors in purchasing a food product, but on what she does in fact deem important.[68]

Required Substandard Labeling

Theoretically, the purpose of the substandard legend which will be required is to set the food apart to avoid consumer confusion with the standard product. Early practice under the McNary-Mapes Amendment was to select a legend which would be of general application and fairly derogatory. The original prescription was "Below U. S. Standard: Low Quality But Not Illegal." [69] Following a further hearing, a somewhat less forbidding legend was substituted for canned fruits. This read "Below U. S. Standard; Good Food—Not High Grade." In 1937 this legend was also applied to substandard canned vegetables.

Following enactment of the 1938 statute, this general substandard legend was continued, *but* in many instances the standard of quality permitted a somewhat softer designation, indicating the particular manner in which the food failed to meet the quality standard. Thus it is possible for a product to be labeled "Below Standard In Quality: Not Tender," or

[68] Compare the preceding discussion on standards of identity, *supra*, p. 552.

[69] An early effort to enjoin the enforcement of this legend failed. *F. Clemens Horst Co. v. Hyde*, (DC Calif. 1931) (unreported).

"—Mixed Sizes," "—Partially Pitted," "—Not Well Peeled," "—Blemished," "—Unevenly Trimmed," "—Partly Crushed or Broken." For vegetables, such designations are permitted as "Below Standard In Quality," "—Excessively Broken Up," "—Poor Color," "—Excessive Peel," "—Excessively Discolored Peas," "—Excessive Foreign Material," "—Not Tender," "—Excessively Mealy."

Since there is unquestionably statutory authority to extend this system of quality standards and substandard label designation to other foods,[70] in many conceivable variations, it is fair to inquire what it accomplishes. There can be no doubt that the system is economically important. It serves to render unsaleable except at a substantial discount, and thus removes from equal competition, that part of the total production which carries the crepe label. For what it is worth, this is indirect evidence of lesser consumer acceptance because of the required label legend. To the same extent, the particular reputation and consumer acceptance of a product as a whole, irrespective of the particular manufacturer, is protected.

Yet there are some who entertain doubts as to the desirability of the entire quality standard program or believe that fundamentally it cannot be said to be in the interest of consumers. They point out that nutritive value is not involved but largely convenience or optical appeal, and urge that this militates against what should be the consumer interest in true food values. Some object that semi-derogatory labeling is unfair to particular sections or producing areas. Others think that a minimum quality standard is insufficient and want all-out governmental vertical quality grading. Lastly, there is a group which thinks that, identity satisfied, quality is so elusive and subjective a thing that it must rest on brand name alone. And for these, the past problems encountered in formulating an effective minimum quality standard offer proof of impracticability. Possible extension of quality standardization beyond canned foods warrants a brief examination of some of these difficulties.

They may be summarized as problems of measurement and of method. Some things cannot be measured objectively. The conventional illustration is "flavor," but there are others which do not readily yield to

[70] "In the future a larger proportion of the standards adopted should be quality standards and standards of fill of container." Callaway, Current Problems in Formulating Food Standards, 2 *Food Drug Cosmetic Law Quarterly* (1947) 138.

any test other than what is usually called an "organoleptic determination." In plain English this means subjective taste or smell. (Seeing usually permits some yardstick to be fixed, such as a color wheel, pH device, etc.) To impound subjective measurement of taste or smell in words for a standard is difficult enough; to enforce the standard is wellnigh impossible.[71] Consequently, the theory is that quality factors, like identity differences, can be recognized only if they are objectively determinable.[72]

To measure, one must establish a method of measurement and decide where to place the controlling line between Standard and Substandard. Determining the method is a scientific matter, but, nevertheless, the method must surmount at least one hurdle if the standard is to be reasonable. The method must be one which the typical manufacturer in the field, or technical men reasonably available to him, can both understand and apply.[73] It must be a method which yields uniform results when practiced by equally competent different people. But an unsolved question is how far the Administrator can go in prescribing a method which the average producer or processor cannot in fact apply because it is technically too difficult, requires highly trained personnel, or is too costly in terms of necessary equipment.

Assuming an adequate and reasonable method for measuring a quality factor, the question of where to draw the line between standard and substandard is *not* a technical question. It should be answered by the examination, according to the prescribed method, of samples reflecting what the consumer would consider acceptable; by trade evaluation and experience, or by any other creditable means of directly or indirectly

[71] Mr. Callaway has mentioned the difficulties in measuring quality factors and has pointed out the problem of subjective determinations: "Graders eat a little of the corn and assign a grade. Such a test of course is not sufficiently definite for use in legal standards where failure to comply may constitute a criminal offense." Callaway, Current Problems in Formulating Food Standards, 2 *Food Drug Cosmetic Law Quarterly* (1947) 130.

[72] On the issue of adulteration, a District Judge has rejected testimony "that the variable sense of smell and taste is more dependable in detecting rot than the microscopic procedure adopted by the Government. Certainly the question of adulteration would rest upon tenuous ground if reliance or conclusion as to the character of the product shipped were bottomed upon conflicting evidence as to the smell or taste of the article sought to be condemned." *United States v. 935 Cases*, 65 F. Supp. 503, 505 (DC Ohio 1946) [*CCH Food Drug Cosmetic Law Reports* ¶ 7019].

[73] Experience with canned foods to date indicates that selection of a technically adequate method to measure some quality factors is not easy. There are still conflicting schools of thought as to which of two methods more accurately and uniformly measures maturity in peas.

showing consumer preferences.[74] (The problem of finding "substantial evidence" of consumer understanding and preference is later considered.)

Much controversy has arisen out of disregard of this distinction between evolving a method of measuring a quality factor and determining where to fix the line between Standard and Substandard. Chemists are qualified to talk about scientific methods; they are not *per se* knowledgeable on consumer preferences. While the point is controlling on what constitutes substantial evidence, it serves also to indicate what should be the rule in formulating a standard of quality. As the writer elsewhere has suggested:

"Scientific witnesses should be permitted to state their opinion about the methods used. Scientific witnesses should *not*, however, be drawn into discussions about the commercial effects of any proposals. Questions of trade practice—questions of what can or cannot be done as a matter of practical cannery operation—should be dealt with by practical cannery witnesses, and this job should not be mixed up with the work of the scientific witnesses.

"There should, so far as possible, be no basis for controversy as to scientific results. Necessarily, there may be differences of opinion as to practical operating questions, and differences of opinion as to the commercial and economic impact of a particular requirement on different areas. But if a given testing method—in the hands of a competent scientist—yields a given result, this should not be a matter for argument among canners.

"The trade [and consumer] testimony should be developed as a measuring rod. Industry evaluation of samples—in terms of commercial grading, in terms of growing conditions, in terms of processing techniques—should be the yardstick for interpretation of the scientific results. For example, if we know that particular samples—according to industry and trade evaluation—are deemed clearly above the standard line, the data offered by scientific witnesses and the data offered by trade witnesses can be correlated. We can say that a given AIS level, for example, is the point at which the trade evaluation would draw the line. If the trade witnesses agree that a given group of samples is clearly substandard, these samples can be identified to tie into a particular level in the scientific data. The only place where differences of opinion may exist should be in the various commercial evaluations and not in the scientific tables against which they will be compared.[75]

A related problem in formulating quality standards is whether compliance will be measured against the single package or can, or determined against some representative group of samples. Legally, the Food and Drug Administration takes the position that *every package* of any food

[74] Here again the issue is not where consumers should consider quality factors, but what they do regard as important. This is undoubtedly what is meant by Mr. Callaway's suggestion that quality standards are approached "from the standpoint of the average consumer." Callaway, Current Problems in Formulating Food Standards, 2 *Food Drug Cosmetic Law Quarterly* (1947) 129.

[75] See *Proceedings of the National Canners Association Technical Sessions*, January 31, 1947, p. 77.

must comply fully with the standard.[76] Its position is predicated on the idea that one consumer getting a poor product is hardly consoled by the knowledge that another might have done better because the average met the standard. Realistically, it is doubtful whether seizure for misbranding occurs where only one unit among many is found defective.[77] But where to establish a standard often turns on this very question whether every package, or the average of a reasonable number of packages, will be measured. A packer might without prohibitive cost undertake that generally in his production a specific requirement can be met. He cannot guarantee that individual units may not vary.[78] How much it will cost to meet a particular requirement—and ultimately increased costs are borne by consumers—may control both reasonableness and consumer interest. While this problem runs through the Act, it becomes peculiarly acute with standards of quality where the typical factors of workmanship are direct functions of cost. How difficult these questions may be for food products other than canned foods is unknown.

III

" . . . reasonable standards of fill of container . . . "

In the absence of any standard of fill of container, it is obviously difficult to enforce Section 403 (d), which renders misbranded any product whose container is so "filled as to be misleading." [79] The relation between this section and Section 403 (h) (2)—which requires special labeling of a product not conforming to the standard of fill—remains to be developed. The consequences of violation are different. Where a standard of fill is formulated, failure to comply means that the product must be relabeled and marked "Below Standard In Fill." But sale of a product

[76] Objection is usually made to any attempt to inquire at the hearing as to how a particular requirement will be enforced. Such reticence is understandable but not helpful in the endeavor to evaluate the reasonableness of a proposed standard of quality.

[77] See *United States v. 935 Cases*, 65 F. Supp. 503 (DC Ohio 1946) [*CCH Food Drug Cosmetic Law Reports* ¶ 7019]; *Gellman v. United States*, 159 F. (2d) 881 (CCA-8; 1947) [*CCH Food Drug Cosmetic Law Reports* ¶ 7045].

[78] One solution may be to formulate the method in terms of examining more than one sample. This has been done to cover what might be called packing accidents. No processor intentionally mixes pitted and unpitted cherries, but pitting machines do get out of adjustment. Thus, while the tolerance for pits and pit fragments is strict, the prescribed method calls for the examination of 24 pounds, which embraces a large number of individual cans. A similar technique is used to measure extraneous vegetable matter in canned beans.

[79] Compare *United States v. Cataldo*, 157 F. (2d) 802 (CCA-1; 1946) [*CCH Food Drug Cosmetic Law Reports* ¶ 7025]; *United States v. 738 Cases Vanilla Pudding* (DC Ariz. 1946) [*CCH Food Drug Cosmetic Law Reports* ¶ 7047].

whose container is so filled as to be misleading under Section 403 (d) requires repackaging to bring it into compliance. Logically, there may be some point of slack filling which is so wanting that sale even with slack-fill labeling would be prohibited by Section 403 (d), and repackaging would be required. And as already noted, in neither case are the truth and completeness of other labeling, e. g., statement of contents, of any relevance.

How far the program of standardizing fill of container for foods will go is difficult to foresee. To date, only nine standards of fill have been promulgated. Each of them applies to a canned food. This may flow from the earlier experience when, under the McNary-Mapes Amendment, such standards were authorized only for canned foods. It seems unrelated to the use of an opaque container; many other foods are so packed; and the standards already issued apply to canned foods in glass. In part, the issuance of fill standards may have to await standards of identity.[80] In some measure administrative reluctance to undertake them may be due to experience with canned foods. This warrants brief review because buried in the story is at least one interesting question of general application.

Superficially, the task of formulating a standard of fill for a canned food might not appear formidable.[81] With discrete units, such as peas contained in a liquid packing medium, it might seem that measuring the head-space—the distance from the top of the can to the level of what was in the can—would suffice. Yet even in this instance it cannot be so simply done. Peas shake down after processing and standing. To be reasonable, the fill standard, though based on measuring head-space, had to provide for a prescribed method of pouring the contents back and forth prior to measurement.

But some vegetables absorb water in processing; others lose it or bleed. Some are not packed so as to be covered by the liquid medium but

[80] This is not necessarily true where the food can be identified without a standard. In two instances, Canned Shrimp and Canned Oysters, standards of fill of container have been issued without there being any standards of identity. For many products, particularly proprietary foods, this procedure would probably not be practicable.

[81] Indeed, as early as 1912, a general fill of container regulation was issued for canned foods. This prescribed that the can "should be as full of food as is practicable for packing and processing without injuring the quality or appearance of the contents." F. I. D. 144, May 22, 1912. As will be seen, this was in reality a manufacturing direction rather than a standard for measuring the fill of a canned product.

are vacuum packed with only a small amount. Other fruits or vegetables come in varying sizes, or their specific gravity varies from time to time. Some can be roughly handled; others are easily crushed. Measuring merely the physical volume of what remained in the can after pouring off the packing medium would not be reasonable. Nor would determining the weight be sufficient. Thus measurement of space occupied by the product, or the drained weight, was feasible only for peas (head space), tomatoes, fruit cocktail, shrimp and oysters (drained weight).[82]

In the case of fruits, these inherent difficulties resulted largely in a pious expression of objective rather than in anything that a lawyer might recognize as a standard. The final prescription in the regulation is that

"The standard fill of container . . . is the maximum quantity [of the particular fruit] which can be sealed in the container and processed by heat to prevent spoilage, without crushing or breaking. . . ."

Backing this rule of "do the best you can" are findings which recite the difficulties. What can be put into a container is found to be dependent

"upon the method of packing and upon the shape, size, degree of maturity, and specific gravity of the units . . ."

Moreover, it is recognized that possible fill is also controlled by

"the size of the container [and] the form, size, firmness of units [and] the necessity for having sufficient liquid to insure proper processing, and other factors."

Nevertheless, the Administrator concluded that

"Assurance to the consumer of a can full of [fruit] can be obtained only by a requirement as to the quantity *put in* the container."

On this basis, the precatory rule of filling so as not to damage what you are packing was incorporated in the regulation.[83] The result is a manufacturing direction and not a measurement which can be applied to the finished product.

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[82] Even in these instances judgment was not easy. For if the drained weight was fixed too high, less packing medium could be used, and the longer processing which would be necessary might disintegrate the product. In one case, now pending, the claim is made that the effect of the standard of fill is to impair the quality of the product.

[83] The findings in each case went on to state that, with "the exception of a comparatively few slack filled cans," those marketed contained as much as the packers, "using reasonably good factory practice," could put in them. Moreover, it was found that canners, in the light of the inherent variables, did their best and employed "inspectors to insure proper filling." These findings perhaps support the result. Even more, they raise some doubt as to the necessity for issuing any standard of fill.

The question lurking in all of this is of far wider interest than the canning industry. It is whether any standard is valid where it obviously can be enforced only by factory inspection. Conceivably, enough data might be assembled to tell from the product where and when you find it whether it was manufactured in a particular way. But this is a complete inversion of purpose. The consumer is interested in what she gets, not in what has been previously done. Where, as in these instances, the variables are so great that later examination cannot yet be correlated to previous practice, it would seem that the standard has meaning only on the assumption that there is virtually continuous factory inspection.[84] That this type of continuous process inspection is authorized by Section 704 is open to doubt. That present enforcement budgets and field practice contemplate it is also questionable.[85] It can be urged that where Congress desired to authorize factory inspection or factory licensing, it always specifically provided for it. (See Section 404 (a).) On the whole, it might be preferable to base standards of fill on methods of examination of the finished product, and, if necessary, to delay their issuance until such methods have been developed.

Where a product does not conform to the standard of fill, the regulation usually provides that it shall bear the general statement of substandard fill. This consists of a label designation in specified type, enclosed in a lined rectangle, containing the legend Below Standard In Fill. Occasionally, however, more specific labeling to indicate the degree to which the can is slack filled may be required.[86] Here, again, there appears to be a wide area of administrative latitude.

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[84] How this type of standard of fill, dependent on method of production, could be enforced against imported products is an intriguing question.

[85] Compare the views of the Chief of the New York Station of the Food and Drug Administration: "The Food and Drug Administration has long held the view that the logical place to find a violation is at the point where it occurs. Objective sampling is wasteful, time consuming, and uncertain of result. The place to determine, for instance, whether a product is being produced under sanitary conditions is at the factory, where all the supporting facts are at the hand of the investigator. For that reason, the work plan of the Food and Drug Administration begins to operate at the factory." McKinnon, Field Observations on Food, Drug, and Cosmetic Law Enforcement, 2 *Food Drug Cosmetic Law Quarterly* (1947) 302, 306.

[86] E. g., a slack filled can of oysters must be labeled, "Below Standard In Fill—A can of this size should contain .... oz. of oysters. This can contains only ..... oz."

IV

Procedural Safeguards

> "It follows that if the order of the Secretary [Administrator] is to be valid, the Government must have placed in the record at the hearing its evidence in support of the action taken and thereby afford opportunity for persons affected to controvert *viva voce* the Government's evidence." House Report No. 2139, Seventy-fifth Congress, third session, April 14, 1938, p. 10.

The procedure for the formulation of food standards has been described as "legislation by litigation." Its requisite elements are: (1) a public hearing pursuant to adequate notice; (2) detailed findings of fact; and (3) the findings and order based on substantial evidence of record. To ensure compliance with these procedural requisites, immediate and direct court review is afforded, and collateral attack is likewise available in any prosecution or seizure based on the standard. Whether these requirements are more advanced, different, or superseded by the Administrative Procedure Act of 1946, may be left to others to develop.[87] Taken together, they appear to reflect the Congressional belief that freedom of enterprise should be the general rule, and governmental regulation the necessary exception. In short, there must be an affirmative basis for regulation. Section 701 is designed to require that the existence of public need be found, that the supporting facts be affirmatively adduced and tested in open hearing, and that administrative determination be made only on an objective examination of what is in the record. The Administrator's judgment on an adequate record is final, but whether he has had enough on which to judge and has judged fairly can be scrutinized.

Whether this prescription for trial methods in rule-making is a practicable mode of government remains to be seen. A consideration of some of the difficulties, which have thus far arisen in the attempt to follow it,

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[87] Generally speaking, little change seems to be required. See Goding, The Impact of the Administrative Procedure Act on the Administration of the Federal Food, Drug, and Cosmetic Act, 2 *Food Drug Cosmetic Law Quarterly* (1947) 139, 150-52; Markel, The Impact Of The Federal Administrative Procedure Act On The Federal Food, Drug, and Cosmetic Act, New York University School of Law Institute Proceedings, *The Federal Administrative Procedure Act and the Administrative Agencies* (1947) 389.

may aid in the evaluation.[88] In anything that is said, it is necessary to remember that the process was novel, that there were few men to do much work, and that it is difficult to act judiciously at all times—particularly when one's own proposals, sincerely believed to be in the public interest, are being assailed with vigor. Plato's hope that for a better world kings might become philosophers and philosophers kings often finds an echo in the suggestion that administrators might learn how to be better judges and reviewing judges perhaps have a stint as administrators.

A. *The Hearing*

As one objector eventually expressed it, "if it ain't in the record, it ain't so." This adequately reflects the statutory insistence that the order be based *only* on substantial evidence of record. In a sense, limiting administrative rule-making only to evidence of record is a paradox. The task of formulating the regulation is entrusted to administrative officials because of their training. They are qualified to judge better because of what they already know. The requirement that the record disclose everything entering into the judgment is somewhat inconsistent and causes the difficulty, later discussed, of determining how large a record must be developed to be adequate.

Nevertheless, the hearings under Section 701 serve a twofold purpose. They afford the vehicle for production of the substantial evidence on which the regulation must be based. It is probably immaterial whether the Government or anyone else introduces such evidence; but without it the technical predicate for a valid order is wanting. Beyond this, there are excellent reasons for a hearing which would have force even if further procedural requirements did not exist. No greater safeguard against ill-advised or arbitrary action exists than to require that he who would act must appear and articulate at least the immediate facts on which he is

[88] "Safeguards must also be institutionalized through machinery and processes. These safeguards largely depend on very high standards of professional service, an effective procedure (remembering that 'in the development of our liberty insistence upon procedural regularity has been a large factor'), easy access to public scrutiny and a constant play of alert public criticism, especially by an informed and spirited bar." Frankfurter, *The Public and Its Government* (Yale University Press, 1933) p. 159.

acting, and why he thinks the desired result will be achieved.[89] The Act, as interpreted in the Rules of Practice for Hearing, goes further and permits cross-examination by anyone.[90] The Attorney-General's Committee early noted that this gives "greater satisfaction to the parties" and affords a "check to which the evidence and arguments may be subjected by counter-evidence, cross-examination, and argument."[91]

Sometimes the proceeding gets out of hand. "Any person" may object, cross-examine, and, unfortunately, argue. The exciting discovery that one need not be a lawyer to cross-examine is too tempting; a secretly harbored conviction that but for fate another Erskine was born, can be gratified. The Presiding Officer is properly indulgent, particularly where the newly born advocate has no counsel. Typically, the witness is harangued; long, winding questions are asked embodying the views and sometimes the autobiography of the questioner; and sometimes the witness is simply badgered. A skillful witness often frustrates the amateur lawyer. The latter quickly picks up superficial tricks; asks that the record be read back; throws his personal discourse into the form of a "hypothetical question"; and insists that he is merely checking the witness' qualifications in his own way. What results is sometimes not a record but chaos.

The result, however amusing, has serious consequences. Facts are confused. The record becomes confounded and costly. There is some evidence or talk on everything. Not only might any finding be supported by testimony, but intelligent court review of this kind of transcribed confusion becomes extremely difficult. In addition, some of the hearings seemed to go on endlessly. One group of cherry canners arrived on the announced date, in response to a notice of a hearing on canned fruits, and could not be heard until a week later. Necessarily, the burden on both the Government and everyone else is measurably increased.[92]

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[89] The Attorney-General's Committee concluded in 1941 that, even where the statute did not so require, "The practice of holding public hearings in the formulation of rules . . . should be continued. . . . Here, as elsewhere in the administrative process, ultimate reliance must be had upon administrative good faith—good faith in not dispensing with hearings when controversial additions to or changes in rules are contemplated." See *Final Report of the Attorney General's Committee on Administrative Procedure* (1941) 108. Compare also the Committee's suggestion that there be an annual report to Congress of all regulations issued or refused. *Id.* 120.

[90] Subject to limitation to prevent undue prolongation of the hearing. Section 2.707.

[91] *Final Report of the Attorney General's Committee on Administrative Procedure* (1941) 110.

[92] The physical size of the record may become particularly troublesome because the present Rules nominally afford only twenty days for filing exceptions to a proposed order. (Section 2.714.) Their preparation in this period, against a lengthy and confused record, is no light task.

Available remedies to secure a better hearing are not easy to suggest. To a large extent, the caliber of the Presiding Officer is determinative. No one suggests that the opportunity to be heard be limited to lawyers. Perhaps more extensive use of informal conferences with the Food Standards Committee—outside the statutory hearing and considerably prior to it—will permit crystallization of issues, will indicate what needs be adduced for a complete record, and will focus attention on what usually are only the few controversial issues.[93]

At the present time, the Committee is a forum for informal presentation of information. In many instances, reluctance exists in frankly presenting the facts and inherent difficulties. This appears to flow from an unwarranted apprehension that either the Food and Drug Administration or industry representatives may in the future be bound by these informal discussions. What is needed is more of the conference table approach—a frank exploration of all of the issues, forthright comment by all present, discussion and evaluation of the available scientific literature, and possibly even suggestions as to how an adequate record may be developed at the hearing. Possibly the Presiding Officer, later to conduct the formal hearing, could attend and become acquainted with the subject matter. Insofar as possible, these pretrial techniques could be profitably pursued.

Other aspects of the hearing procedure are currently being reviewed by the Administration and by a committee of the Food and Drug Section. Mr. Markel has discussed the problem of admitting scientific treatises in evidence.[94] This is part of the basic difficulty that in these hearings witnesses usually testify against a subsumed background of industry information. What everybody is supposed to know is not of record, nor is it feasible to develop a comprehensive treatise on the art of canning, bread baking, or flour milling. Yet often it is revealed after the hearing that the inarticulated premises of Government and industry witnesses were different. Here, again, the skill of the Presiding Officer, and of counsel, together with the advance identification of controversial issues, may be helpful.

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[93] In its statement on Organization and Procedures, published pursuant to the Administrative Procedure Act, the Agency said: "The Food Standards Committee usually holds informal public hearings, after appropriate notice, on proposals to formulate definitions and standards of identity for food to be announced for formal public hearings." 11 *Federal Register* 177A-543, September 11, 1946. This work could be expanded and this statement amplified.

[94] Markel, Federal Food Standards, 1 *Food Drug Cosmetic Law Quarterly* (1946) 39.

Related to the kind of record which may be evolved is the question of notice. The statute requires thirty days' notice setting "forth the proposal in *general terms.*" How much notice is enough is both a question of fundamental fairness and likewise a legal prerequisite to a valid order. In several early instances, the published proposed regulation embodied requirements which did not appear in the notice, were not mooted at the hearing, and were deemed important.[95] (The propriety of the notice given has bearing also on the problem of so-called negative findings discussed later.)

Whether thirty days' notice is sufficient depends upon what is done informally prior to hearing. Insofar as the Government is concerned, the expanded use of the Food Standards Committee exploratory meetings is highly desirable. Beyond this, early official announcement of the *intention* to call a hearing—often given and a highly desirable practice—will permit adequate preparation and participation by industry. This is the touchstone, not only for protection of a particular interest, but also to facilitate the administrative job. To it final reference will be made.

Other suggestions to improve the hearing are often advanced. The revision of the Rules to permit interchange of scientific papers, use of which is contemplated, might be desirable; but since the number of "other parties" is indefinite, some type of public or published service will be necessary. Other pretrial techniques are not readily adaptable. Mr. Markel's suggestion[96] that the method specified in Section 507 for penicillin and streptomycin standards might be used, is provocative in that it reserves for public hearing only the controversial issues. This will necessitate a revision of the Act, and there is some doubt whether a procedure, narrowly channelized and founded on protection of public health, is adaptable to resolution of the different and complex economic issues concerned in food standards. What might happen would be the filing of exceptions to so many things that the resulting hearing would be as comprehensive as that now provided. Lastly, it seems clear that the burden of establishing the facts underlying the need for the regulation would shift. With expansion of the conference procedure through the Food Standards

[95] E. g., the proposal to require that "cane sugar" and "beet sugar" be separately identified on the label of canned fruits. In this instance, the point had not even been raised in informal discussion.

[96] A Postscript to the Papers of the Second Annual Meeting of the Section on Food, Drug and Cosmetic Law, 2 *Food Drug Cosmetic Law Quarterly* (1947) 216, at 225.

Committee, a further period for trial and development of the present method prescribed in Section 701 might be preferable to statutory changes.

B. *Detailed Findings of Fact*

> "The administrative process will best be vindicated by clarity in its exercise." *Phelps Dodge Corp. v. Labor Board*, 313 U. S. 177, 197 (1941).

The finding of facts by a trial judge is one of the most sensitive and delicate parts of the judicial art. Respect to it is paid in Rule 52 of the Federal Rules of Civil Procedure [97] and in a multitude of appellate decisions.[98] Transposition of the phrase to administrative activity should not obscure important differences in function. Usually, the trial judge sees and hears the witnesses, and seldom is his judgment on credibility disturbed. In the administrative process under Section 701, the Presiding Officer alone meets the witnesses, and the Administrator's decisions (assuming his detailed exploration of the record on key issues) are made on an impersonal transcript. A judge is aided by proposed findings filed by the parties; and this practice, though permitted, is not followed extensively in standard-making proceedings. Moreover, the trial judge endeavors to make findings on all controverted issues: he seeks to record his judgment and present an adequate picture of all of the relevant testimony. What sometimes happens in food standard findings will be reviewed. But more important is the fact, unavoidable in rule-making, that in effect those who are parties to a controversy ultimately participate in its decision and in the preparation of the findings on which in large measure judicial review will turn.[99]

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[97] Rule 52 (a) specifies that findings of fact by a trial court shall not be set aside unless clearly erroneous.

[98] E. g., *Alabama Power Co. v. Ickes*, 302 U. S. 464, 477 (1938); *United States v. Aluminum Co. of America*, 148 F. 2d 416, 433 (1945). Comparable respect is not always extended to findings of ultimate fact which in reality involve applying a rule of law to particular facts of record. See *Baumgartner v. United States*, 322 U. S. 665, 670 (1944); Stern, Review of Findings of Administrators, Judges and Juries, 58 *Harvard Law Review* (1944) 70, 113.

[99] For an interesting critique of the earlier "ivory tower" handling of proposed findings and the collective character of present administrative judgments, see Markel, The Import of the Federal Administrative Procedure Act on the Federal Food, Drug, and Cosmetic Act, New York University School of Law Institute Proceedings, *The Federal Administrative Procedure Act and the Administrative Agencies* (1947) 394-96. Formal recitation by way of conclusion that "honesty and fair dealing" will be promoted should be distinguished from requisite detailed findings of fact. Though the opinion is far from clear, *Twin City Milk Producers Ass'n v. McNutt*, 123 F. (2d) 396, 398 (CCA-8; 1941), suggests that this recital is not required by

Consequently, the administrative findings, both proposed and final, made in response to the statutory requirement that they be *detailed*, offer a revealing index of how evidence is treated. Without doubt, most lawyers are prone to view critically any findings against them made after a long hearing. But the findings proposed and ultimately made in a few standard proceedings are unduly provocative. In some respects they invite discussion and warrant suggestions for improvement.

In the hands of a critic, the occasional is often distorted into the typical. Lest this charge be made, it should be understood that the criticisms voiced in this discussion of findings and substantial evidence are fortunately not very often applicable. But one troublesome episode overshadows a wide area of meticulous effort. Because this is true, instances which have evoked doubts are worth examination by those who are interested in improving the procedure. Equally important is the fact that in almost every case, the ultimate judgment is sound; how it appears to have been reached, as reflected by the findings, is the source of difficulty. Not unlike people, administrative agencies acquire reputations with the courts and the public as much from the unusual and apparent as from the typical and actual.

In the first place, there is a tendency to write up the evidence to support the decision and to write down or disregard the evidence the other way. Whether there is "substantial evidence" is a separate and controlling question. But it cannot be answered by emulating the technique of Greatauk in "Penguin Island" in drawing findings. The point may be delicate, yet it preferably should be fairly faced to ensure validity and to command respect for what are intrinsically fair and sound judgments. In one early proceeding, the proposed findings devoted five and one-half columns of the Federal Register to summarizing the testimony of one Government witness, and made no mention of the testimony of four qualified industry witnesses, and only brief mention of a fifth on the same issues. This may be a form of advocacy, but it is hardly adequate finding as to the facts of record.

Another charge of the same kind is that what is in the record is neither quantitatively nor qualitatively reflected in the findings to disclose

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law, but is simply an added control imposed by the courts "as their own convenience and orderly functioning fittingly suggest. . . ." If so, the added requirement is hardly onerous.

the judgment made. Legally, it is clear that one may not pick and choose in the record, disregarding or ignoring the relevant evidence of anybody. Palpable neglect to consider testimony constitutes arbitrary action which will vitiate the regulation. This is the dividing line between law and arbitrary power. As the court said in the *Staley* case, "the requirement of essential findings does not require an impracticable exactness" yet "the right to present evidence is a barren one if the trier of facts fails to consider it."[100] But in many instances the point is not so much what decision has been made, but how it appears to have been made. Where findings on a controversial issue consistently dispose of numerous industry witnesses by reciting merely that "there is *some* evidence" and invariably sum up a Government witness' testimony by a categorical statement of the fact to which he testified, it is difficult to convince critics that the record is being evaluated without bias.[101] No matter what the record is in fact, this kind of drafting of findings does an injustice both to those who testify and those who decide. In writing his opinions, Mr. Justice Brandeis was most concerned that he had fairly considered and adequately discussed every arguable point made by the losing party. A comparable concept in the preparation of findings would pay dividends in winning an understanding both of the difficulty and the fairness of the administrative decision.

It is possible that in some measure these troublesome techniques may flow from administrative timidity or reticence. Often there is directly conflicting testimony by equally competent witnesses. To decide an issue of fact, one man may have to be believed and another disbelieved. Instead of a candid finding on credibility—that of conflicting testimony the Administrator has accepted one view rather than the other[102]—there may be the tendency to write up one view in a finding and write down the other. This may be easier or more gentle, but probably is not worth the price it exacts in criticism and misunderstanding.

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[100] *Staley Mfgr. Co. v. Secretary*, 120 F. (2d) 258, 261 (CCA-7; 1941). Proposed findings are usually issued with record and exhibit references, and the additional following hedge: "The page references to certain relevant portions of the record are for the convenience of the reader. However, the findings of fact are not based solely on that portion of the record to which reference is made but upon consideration of all the evidence of record." Occasionally, this qualification is not included.

[101] Though unwarranted, this feeling gives rise to such statements as, "Most manufacturers enter these hearings with the feeling they have two strikes on them before they start." Peters, Are Food Standards Assets or Liabilities?, 18 *Food Industries* (1946).

[102] A forthright rejection of evidence as not credible is sometimes made in the case of affidavits, but seldom does the issue appear to be faced with a witness's testimony.

In the second place, there is some confusion on the subject of negative findings. These take the form of conclusions from the *absence* of evidence. Inclusion of an optional ingredient is requested. Its use is shown and nothing else. On this record, may the Administrator find, as once proposed, that there is no basis for determining that permitting use of the ingredient in the product will promote honesty and fair dealing in the interest of consumers? [103] A similar question may arise where an amendment is asked on the ground that a standard has in practice turned out to be unreasonable. This issue will loom more acutely on requested revision of standards where new ingredients are proposed.[104] The pitfall lies in failure to remember that a refusal to change the standard is equivalent to an affirmative regulation outlawing use of the ingredient. Of course, if an ingredient is deleterious, it may be forbidden if the record adequately discloses that it is not wholesome. Or if the evidence demonstrates that its use will lend itself to fraud, or insanitary practices, or concealment of inferiority, these are proper reasons for excluding an ingredient. But where none of this is shown on the record, can the Administrator lawfully refuse to recognize an ingredient, or refuse to amend a standard of identity, merely by finding that there is no evidence that to do so will promote honesty and fair dealing in the interest of consumers? It would seem that a negative finding of this sort can hardly support a change in the fundamental rule that administrative regulation requires an affirmative showing of public need. Forecasting what the substantive decision will be may be hazardous, but it seems clear that affirmative regulation cannot rest on negative findings.[105]

C. *Substantial Evidence of Record*

"*Mr. Robertson.* In referring to the honest-to-God investigation of what is and what is not substantial evidence, would not the court also

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[103] In the *Staley* case the record did not appear to show prior commercial use.

[104] The Rules of Practice provide that those who want the standard changed are first heard, but this cannot change the fundamental requirement that any regulation must be based on facts showing its need.

[105] There is little basis for supposing that the rule is different for original standardization regulations than for amendments. Original exclusion must rest on record evidence showing the necessity for outlawing use of the ingredient. But if it is argued that any subsequent change throws the burden on the applicant for change, the result would be to nullify in large measure the provisions of Section 701 for amendment of standards. Any wide use of the negative-finding technique would strengthen the argument that standards have the effect of freezing methods of manufacture.

> give consideration to evidence of the ultimate fact which the Secretary [Administrator] is finding as distinguished from opinion evidence?
>
> "*Mr. Lea.* That is very true. Opinion evidence might become worthless in view of concrete indisputable direct evidence." *House Debate,* June 13, 1938, 83 *Congressional Record* 9097.[106]

The language of Section 701 makes it clear that any regulation must be based "*only* on *substantial evidence* of record at the hearing." It is a fair observation that, in almost all contested standard proceedings, vigorous exceptions have been filed challenging the proposed order on the ground that substantial evidence was lacking. Despite the record of judicial approval,[107] it is on this issue that the proceedings up to this time are possibly subject to warranted criticism.

Court decisions offer compelling general language as to the meaning of "substantial evidence." The road through the cases is long and need not be traversed beyond the cogent remark of Mr. Justice Stone that "Substantial evidence is more than a scintilla, and must do more than create a suspicion of the existence of the fact to be established." [108] What has evoked criticism have been practical questions of proof which have emerged in actual proceedings. They are important wholly apart from whether they might run the gamut of judicial scrutiny on appeal. Eventually, some of them might endanger the entire process.

Cardinal is the problem of opinion evidence. The Rules of Practice hopefully prescribe that, "opinion evidence shall be admitted when the presiding officer is satisfied that the witness is properly qualified" (Section 2.707 (d)). This throws no light whatever on the weight to be given such evidence. In the very early proceedings, particularly those to stand-

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[106] There was considerable Congressional apprehension about opinion evidence, typified by the following:

"*Mr. Buck.* 'Substantial' is not going to mean evidence based on a lot of opinions that some bureaucrats would seem to want to offer?

"*Mr. Lea.* No." 83 *Congressional Record* 9097.

[107] Out of nine cases, only one standard has been invalidated by a District Court, see *United States v. Lord-Mott Co.*, 57 F. Supp. 128 (DC Md. 1944).

[108] *National Labor Relations Board v. Columbian Enameling Co.*, 306 U. S. 292, 300 (1939). See also *Consolidated Edison Co. v. National Labor Relations Board*, 305 U. S. 197, 229 (1938); and, generally, Stephens, *Administrative Tribunals and the Rules of Evidence* (Cambridge, 1933).

ardized canned foods, a witness would describe the product, advert briefly to the proposed standard, and then be asked,

"Based on your judgment, training, and experience, do you believe that the proposed standard is reasonable and will promote honesty and fair dealing in the interest of consumers?"

The not unexpected affirmative answer was usually cited as substantial evidence. Where a controversy developed, the early tendency was to build up the expert instead of the facts, and often the final order was based more on one man's opinion about the facts (largely subsumed) than on the facts themselves.

Not unnaturally, this led either to an attempt to discredit the qualifications of the opposing challenged expert or to the effort to produce a better one to overbalance him.[109] It looked for a time as though hearings would mean and substantial evidence consist largely of a battle of experts. In this game, the Government usually came off best.

At the heart of this controversial area is the use of the Administrator's own employees as expert witnesses.[110] Difficult indeed has been the lot of one Departmental official who has been put in the unique position of being presented and qualified as an expert on flour, bread, cheese, evaporated milk, tomatoes, peas, oleomargarine, oysters, beans, corn meal and most other products. In each instance, his assigned task has been to present general observations, to qualify himself as an expert, and to offer opinion testimony as presumably responsive to the data presented by others. In large measure, these difficulties derive from the limitations of staff and a commendable abundance of zeal in the advancement of this standard-making program. Yet these factors do not lessen the task of industry counsel, who must reluctantly seek to establish lack of qualification. Although, with all due deference, no one could be an expert on all these subjects, the gentleman in question is a splendid witness and the job of cross-examination is far from easy. Nor does lack of staff change the fact that anyone's opinion, absent factual basis, is not substantial evidence.

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[109] Unfortunately, this sometimes led to unhappy cross-examination, to discussions *ad homine*, and even to charges of "inspired evidence."

[110] In one instance, it was suggested that the entire order was void because the same employees were charged with having prepared the proposal, testified as experts in favor of it, and thereafter participated in drafting the proposed regulation. It is doubtful whether such separation of functions is legally essential to validity. But the issue remains as to the substantiality as evidence of the Departmental employee's opinions.

No one challenges the technical competence of Departmental experts on questions of technical fact—what testing methods are available, what chemical analysis of a product has shown, or what the scientific literature discloses. This is their job; these men are skilled; and this basic data is essential for an adequate record. It is only where opinions are substituted for testimony as to facts, where these opinions concern non-technical issues such as consumer understanding or economic effect, and particularly where the opinion advanced is in reality a judgment on the entire case, that procedural regularity can be questioned and the issue of substantial evidence be raised.[111]

Thus, while Section 701 does not preclude determination of technical questions by competent experts rather than by lawyers or courts, it does not contemplate that unsupported conclusions, even by a government expert, shall control. As once put, the procedure envisages that the expert shall be on tap, not on top. Where decision rests on "opinion" evidence—even on "judgment, training and experience" as a ritual formula—mere opinion alone is *not* substantial evidence. On any issue of reasonableness, for example, it is obvious that government experts, if their competence is established, may honestly express one opinion, and equally experienced and competent industry experts may with equal honesty express another. But unless the standard-making procedure is to revert to the ancient trial by compurgation or to a contest as to who can marshal the greatest number of experts with opinions, resort must be had in such cases to the underlying facts on which such opinions are based.

Two other things need be said on this point. On no theory of the law of evidence or the fundamental propriety of an administrative proceeding can the opinions of any witness, given merely by way of comment upon the fact testimony of others, be deemed to have any substantial probative value in negativing the existence of the fact. It is doubtful

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[111] Professor Laski, certainly no opponent of the administrative process, has taken the position that on any problem of government the ultimate judgment should be exercised not by the expert but by the amateur. He insists that the expert "dislikes the appearance of novel views," possesses an "expert's caste-spirit," and "in fact, simply by reason of his immersion in a routine, tends to lack flexibility of mind once he approaches the margins of his special theme."

The plain man, asserts Professor Laski, "represents, at his best, supreme common sense in relation to *expertise*. He indicates the limits of the possible. He measures what can be done in terms of the material at his disposal. . . . The importance of the plain man's judgment is, in short, the foundation upon which the expert, if he is to be successful, must seek to build." See Laski, The Limitations of The Expert, 162 *Harper's Magazine* (1930) 101, reprinted in Gellhorn, *Administrative Law* (1947) 64, 67, 69.

whether there can properly be resort to opinion evidence except where the question is so technical that an ordinary man would not be qualified to draw conclusions from the facts presented. This would certainly be true on any such issue as to what was the common or usual name of a food product. To ascertain the name by which a food is known and labeled is not a complicated technical inquiry necessitating experts, but requires merely the reporting of simple facts. This, again, does not mean that the Department's technical staff may not exercise a judgment on technical data. It means that there must always be adequate data for judgment. Speculation even on technical questions is still speculation, and can play no proper part in law making on facts.[112]

But hardly debatable is the contention—which has been so often advanced that it may sometimes have been true—that a government witness' opinion has been considered as substantial evidence even when numerous opposing witnesses testified to facts contradicting his opinion. In such circumstances, the unsupported opinion appears to be a hollow reed upon which to base an administrative determination and, if presented on a clear record, will undoubtedly draw judicial disapproval.

A somewhat related question of substantiality arises out of testimony concerning laboratory experiments. Here the usual charge is that what has been done is a scientific curiosity unrelated to commercial operation or problems. The issue is not one of personal qualification but, again, of fact. It exemplifies the broader question of the difference between contradicted and uncontradicted evidence. To a high degree, any fact asserted on the record, and neither challenged nor contradicted by other facts, may be accepted.[113] But where there is controversy and contradiction, the task of decision turns on winnowing out the fact from opinion or the true from the false. An experiment may be accurate. It may or may not be a proper analogue to commercial practice. These are two separate questions resting on different facts. Opinions on each issue may be helpful, but in the face of actual data they should not be controlling or regarded as substantial evidence. Thus a laboratory experiment may be

[112] By way of illustration, a personal predeliction for a particular name for a food is neither a fact nor a scientific opinion, no matter who offers it.

[113] Recognition of the value of cross-examination underlies the caveat in the rules about the weight which may be attached to affidavits. Mr. Markel's observation that affidavits are of limited value can hardly be challenged. Markel, Federal Food Standards, 1 *Food Drug Cosmetic Law Quarterly* (1946) 39. They are, however, useful where background information, such as production figures, stocks on hand, etc., are needed and cannot be directly obtained for the record.

highly illuminating. Yet where the record discloses that it departed radically from commercial practices, it is not substantial evidence as to the reasonableness of a regulation containing requirements founded upon such experiment.

Any determination as to what is substantial evidence means that testimony must be realistically evaluated. It is here that the lawyer is often puzzled by the apparent failure of some administrative officials to appreciate what any judge, and most juries, innately understand. The hearsay rule is not applicable to standard hearings. But this does not mean that anything presented at a hearing is substantial evidence. To offer one of many examples: on the issue whether a required fill had resulted in impairment of the quality of a canned product, testimony was presented summarizing the results of a survey by Food and Drug field inspectors. These officially identified gentlemen had called upon distributors and inquired whether the quality of what was currently being sold was poorer than what had formerly been sold. Most of those asked said, "No"; the tabulation was offered as evidence; and, in the face of conflicting direct testimony, made the basis for a proposed finding that quality had not been impaired. This is asking a lot of human nature. Without exploring the subtleties of the *res gestae* exception to the hearsay rule, or debating whether citizens always give honest answers to government inspectors, the absence of any opportunity to cross-examine such tabulated hearsay, secured under these circumstances, destroys its value as substantial evidence.

Occasionally found is the apparent acceptance of sheer speculation as substantial evidence. This takes the form of earnest testimony that if a particular practice should have a particular result, then it would be disadvantageous to the consumer. Cross-examination may reveal complete doubt as to whether the assumed result ever occurs. Yet this type of "if it happens, and I don't know whether it does happen" testimony is sometimes taken as substantial evidence that the results will happen, and used as the foundation for a regulation designed to prevent their occurrence.

All of these questions come into sharp focus on the controlling ultimate issue of what will promote honesty and fair dealing in the interest of consumers. Decision requires some facts as to what the consumer thinks, what her interests are, what are her prevailing concepts as to the identity and composition of foods, what might or might not cause confu-

sion, and what she might or might not deem acceptable in a food product. This is the most elusive corner of the whole problem of substantial evidence in these proceedings. However competent technically, no matter how happy their individual experiences may have been, government chemists, bacteriologists, or other scientific experts are not *per se* qualified to answer these questions. By the same token, neither are canners or other food manufacturers. Trade facts concerning the distribution and expanding acceptance of a particular product are relevant to the issue but may not be controlling.

The collective noun, consumer, has content but not specific identity. Its range covers all sections of the country, all economic levels, all tastes and preferences, and presumably all standards of cooking. To impound the collective opinion of so vast a group necessitates either the use of informed experts on these specific matters or some survey technique. As previously noted, experts should carry no more weight than their experience and information. And *substantial* evidence is required. Individual housewives are not qualified to answer for a nation of consumers. Nor by any realistic standards can the testimony of organization representatives be always accepted as the equivalent of a poll of their membership. Seldom do they testify to anything that properly could be termed evidence. Too often the venturesome effort at cross-examination of these ladies reveals that they carry a broad mandate and that the authority and discretion delegated to them to speak for all American women has apparently no bounds. Occasionally they even assert knowledge of broad consumer views with respect to technical niceties first developed earlier in the hearings.

Qualified experts with wide knowledge of consumer preferences have been helpful. Yet often, if called without previous opportunity for inquiry, they candidly disclaim knowledge of consumer preferences on specific points. And the invitation to make a preliminary canvass often results in later argument about who underwrote the project, the objectivity of the method, and the acceptability of the evidence.[114]

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[114] There appears to be considerable reluctance to answer questions where the informant is told that the information may be produced in a governmental inquiry. Many people have a strange fear that this will bring down upon them representatives of the F. B. I. Others do not want to be put in the position of opposing the views of any governmental agency. Yet failure to state the purpose for which questions are asked is often fatal; and in one instance a letter survey made by a qualified nutritionist, on a confidential basis, was refused admission because the names of those who replied were not revealed. On the other hand, a more or less informal canvassing of consumer opinions by cherry packers was admitted.

Perhaps the answer lies in carefully organized opinion polls. These are costly, and the problems of formulating unloaded questions and securing an adequate statistical base open a wide door for challenge. Yet, without adequate direct canvassing of consumer preference, some crucial issues may in reality have to be resolved by unenlightened speculation—even by experts. Perhaps some type of poll can be devised which, while not conclusive, will still be helpful.[115] Mr. Markel [116] has suggested that any properly representative and fairly conducted poll is good evidence "if the results are such that the ordinary prudent business man would rely on them in making business decisions." His further suggestion is that a poll planned jointly by government and industry counsel would be adequate. Yet this still leaves the vital question as to whether the results of such polls can be taken as "substantial evidence," and, more important, whether, in the absence of this type of data, the opinions of one set of witnesses are of any greater value than the conflicting opinions of another set. On this issue, the answer may lie in a paraphrase of Mr. Justice Holmes that one lone fact is worth a ton of opinion.

V

Conclusion

> "If we look at it realistically, we see that the formulation of food standards is a joint endeavor by government and industry. The government is looking out for the interests of consumers. The industry has its own viewpoint, but there should be nothing basically different in industry's viewpoint, it seems to me, and the government's viewpoint, because consumers are the industry's customers and anything an industry can do to

[115] It is interesting to observe that in two consumer preference studies, to be conducted by the Bureau of Agricultural Economics under the Research and Marketing Act of 1946, on potatoes and citrus fruits, scientific door-to-door polls of housewives and hotel and restaurant buyers are scheduled with a force of 4,000 investigators. See *Food Field Reporter*, October 13, 1947, p. 21. Query: Does the answer lie in further appropriations?

[116] Markel, Federal Food Standards, 1 *Food Drug Cosmetic Law Quarterly* (1946) 39.

> promote honesty and fair dealing in the interest of consumers is to a long-time benefit of that industry."[117]

These discussions will have wholly missed their mark if they have not developed several overall conclusions. Proffering them may be regarded by some as presumptive preaching or the voicing of illusory hopes. Yet one cannot participate extensively in standard proceedings without coming to believe that all concerned could do better. The job of formulating adequate and reasonable standards of identity, quality, and fill of container for foods is tremendously difficult. It requires a great measure of cooperation and an understanding approach both by government officials and by industry. The statute contemplates that industry should play an active part in their formulation, and good standards will result and needless controversy diminish only to the extent that this objective is realized.

As for industry, it should not be difficult to enlist the necessary effort. The time has passed when food manufacturers can be unaware of the economic importance of the standardization program or retain any doubt that it can embrace every food product. What is done before, during, and on the basis of the hearings will have an impact upon the operations of the affected manufacturers for decades to come. Maintenance of the integrity of particular foods is as important to those who make them as it is to those who consume them. Appreciation of the elusive character of the controlling economic issues upon which standards depend should lead to an alert interest in the program and to an active participation in the work of formulating any standard in which a particular manufacturer is interested. The notion, sometimes encountered, that in governmental inquiries one should "say as little as possible" contributes nothing and will inevitably boomerang. Industry participation in standard making will be effective largely to the extent that it results in the presentation of complete information upon which administrative judgment can be exercised. In this effort, collective activity in necessary research through trade associations is not only permissible but is also often the most effective method.

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[117] Associate Commissioner Charles W. Crawford, informal remarks at the second annual meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association, January, 1947, quoted in 2 *Food Drug Cosmetic Law Quarterly* (1947) 221.

Insofar as the government is concerned, the observation might be ventured that no proposals for particular standards be issued until the underlying necessary work has been done. This carries as a corollary not only that adequate data be assembled in cooperation with industry, but also that some real need for the standard be demonstrated. Informal discussion and even possibly joint research with industry would be helpful. Exploration and exposure of troublesome issues should be made well in advance, and the Food Standards Committee procedure be fully utilized further to iron out in advance as many differences as possible. A more judicial approach to hearings, to the evaluation of evidence, and in the formulation of findings would in many instances be helpful not only to ensure technical validity but also as important instruments of better public relations.

Lastly, it may be a strange observation for a lawyer to urge that neither group should approach the problem as litigants. Government officials are not here dealing with malefactors whose practices endanger the public health. They are not policing or prosecuting, but carrying out delegated legislative functions. In doing so they are dealing with economic issues of great difficulty and of vital impact on those they affect. On its part, industry must understand that it is not being prosecuted by a regulatory agency but instead is being afforded a splendid opportunity to participate in the program which Congress has ordained.

[*The End*]

ENACTMENT OF NUTRITION STANDARDS SUGGESTED

Enactment of laws to maintain standards of nutrition comparable to the pure food laws was suggested by Basil O'Connor, national chairman of the American Red Cross, at a dinner of the National Vitamin Foundation, because "a majority of Americans suffer from nutritional deficiencies." He called for what he termed "insured nutrition" on the basis that standards of nutrition are as important as standards of purity (Release of National Vitamin Foundation).

The Sanitation Program of the National Canners Association...

J. Russell Esty and E. J. Cameron

SHORTLY AFTER THE FORMATION of the National Canners Association in 1907, the members set up in the By-Laws certain qualifications for active membership, among which were: "To maintain a sanitary canning plant and to conduct the same in a sanitary manner." In 1913, the year its laboratory was established in Washington, D. C., the National Canners Association appointed a committee on Sanitation, which recommended a set of sanitary requirements for canneries at the 1914 Convention of the Association. In 1923, a sanitary code was adopted. For nearly 30 years sanitation has been a very important consideration in the determination of proper cooks to safeguard the health of the consumer. Waste disposal is also a matter of concern to canners with respect to sanitation. Hence, for a long time the sanitation of canneries has been considered important by the industry, and canners have become increasingly aware of such benefits of sanitation as more efficient operation, better workmanship, fewer accidents and greatly improved personnel relationships.

Doctor K. F. Meyer, in a paper on "How California Instituted Sanitary Control in Food Plants," [1] read at the annual meeting of the Institute of Food Technologists, June 3, 1947, presented some of the history of the procedures which California has found satisfactory in the sanitary control of food plants, reviewed the value of blending educational and regulatory policies, and offered practical suggestions to be followed in the institution of a sanitary program. At the outset, he asserted that, "There is nothing new or revolutionary which can be contributed to the sanitation in food processing plants; it is only necessary to see that the rather commonplace facts of environmental sanitation are applied," and that the word "control," appearing in the title, "implies police measures when in reality the sanitation program under discussion is built upon sound educational and organizational principles; this aspect may possibly

[1] I *Food Technology* (1947) 354-363.

Mr. Cameron is Director of the National Canners Association Research Laboratories in Washington, D. C. Mr. Esty is with the San Francisco branch.

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be new." Commenting on the California program further, he states that, "These preliminary successes, however, should not create a false feeling of achievement for the sanitation principles now being taught and carried into operation are based upon knowledge and scientific facts discovered and made available 30-40 years ago." And, also, "There are today certain barriers to real progress in sanitation which must go down before advances fundamental to that progress can be made." He referred to the consideration from the sanitation point of view of such matters as the scientific planning of new construction and requirements for adequate and proper lighting, studies in industrial hygiene, research on fungicidal paints, cleaning materials and procedures, etc. He also commended the canning industry for its present sanitation program, now in its third year, which is being conducted by the Research Laboratories of the National Canners Association.

In compliance with the request for an article summarizing the actions to date on sanitation in canned foods production, the following is submitted with the hope that not only will it be informative, but, also, that it will encourage more thoughtful consideration of sanitation in food production generally, and that it will stimulate further research on problems pertinent to better plant sanitation.

In recent years, largely due to the demands for maximum production, the maintenance of sanitation has become a dominant problem. Canneries, making an "all-out" effort to preserve food for off-season consumption during World War II, produced quantities of foodstuffs far in excess of their normal capacity, with many inexperienced employees, inadequate supervision and, in many instances, with run-down equipment. Also, with this increased production, there has been a tendency in the industry to minimize the fact that each individual can should be produced under conditions of uniform sanitary handling.

Furthermore, many canners had failed to realize that, in the Federal Food, Drug and Cosmetic Act of 1938, in addition to protection of his health, the consumer has the right to protection against practices which are offenses only to his aesthetic sense, that provision was made in the 1938 Act for considering a food to be adulterated even if there is only a possibility of its becoming contaminated with filth, and, also, that it is no

longer necessary to establish the presence of filth or an injurious substance in the product. Thus, with the enacting of the present law, a new significance was given to the sanitation of foods.

Acting on the authority provided, government inspectors, versed in the sanitary sciences and sanitary practices, with the aid of laboratory technicians employing microbiological and chemical methods, proceeded to check up on preserved foods and discovered that some unsatisfactory conditions existed within the industry. However, to the casual observer and to those responsible for production, some of these conditions had not been recognized heretofore as having any particular significance.

Sanitary Surveys

During the latter part of 1944, the industry became cognizant of violations to the Act through libel actions alleging that certain products had been produced, prepared, packed, or held under insanitary conditions. Accordingly, a preliminary "spot" survey was made for the industry in January 1945 by E. S. Doyle, a trained sanitarian, of sanitary conditions in representative canneries operating at that time. The survey indicated that in every plant visited environmental conditions were imperfect from a sanitary viewpoint, and that the managements were not fully aware of the fact that good housekeeping means sanitation.

These significant findings were reported promptly to the National Canners Association's Advisory Committees, and immediately the Directors of the research laboratories in Washington, D. C., and San Francisco, were authorized to conduct an educational campaign on a national scale in order to promote a modern sanitation program for the entire industry, regardless of membership in the National Canners Association. Trained sanitarians were added to the staffs of both laboratories and they proceeded to learn at first hand more about the problem.

The program was inaugurated by conducting voluntary, critical, and confidential sanitary surveys in various canning centers. In addition to insanitary conditions that might contaminate the product, those that related to employee morale, quality of product, and efficiency of operations were also included. The surveys established promptly the need for a balance between production and sanitation, and the fact that sanitation is fundamental to all phases of food preservation, from the choice of the cannery site to the delivery of the product to the housewife in its sealed container.

In surveying individual plants, an attempt was made at completeness in order to provide as much information as possible regarding sanitary conditions. A detailed sanitary survey form was developed for recording the observations, in order not to overlook anything of importance. The form also served to make the managements conscious of the intricacies inherent in the sanitation program. Many things observed were minor, but, being considered relatively important by trained sanitarians, they were included in the report for further consideration. On the other hand, it was appreciated that any single survey has limited value because many possibilities and many occurrences are not apparent in a limited inspection, nor is it possible in a short time to understand individual operating difficulties.

The surveys showed that problems which were common throughout the canning industry varied in degree, and also that there were specific problems incident to the packing of certain products. Representative of general industry problems may be mentioned protection of ingredients, plant lighting, steam and moisture removal and disposal of cannery wastes.

In many cases it appeared that there was a definite need to recognize signs of rodents, to appreciate the importance of "building out" the rodent, to handle poisons properly, and to understand how to carry on eradication programs within and around the plant. In those cases where the plant had in its employ a man with the time and authority to carry on rodent-stopping practices and eradication procedures, it was observed that the control was satisfactory.

In a good many plants it was observed that a need existed for a study of plant lighting from the standpoint of the light intensities necessary on various work surfaces, and a consideration of such factors as color, and type of belt, shadows, glare, reflection, paint colors, relation of overall plant lighting to that needed for a specific task, type of lighting fixtures to be used, etc. In addition, it appeared that the importance of the overall plant lighting was very often overlooked in its relation to plant housekeeping and general plant sanitation.

The problem of steam and moisture removal usually varied with the construction of the buildings, those with low ceilings and with second or third floors giving the most trouble. The use of large amounts of water and the consequent excessively wet floors presented problems in many

plants. The handling of certain products also presented difficult problems in the matter of disposal of waste, and, allied to the waste disposal problem, was the need for better cleaning of waste containers such as barrels, boxes, and hoppers, in order to keep down objectionable odors and the insect population.

Training Course in Sanitation

Expert technical assistance was unnecessary to bring about improvement and correction of certain conditions observed by the survey, but the investigation clearly demonstrated the need for trained sanitation supervisors in canneries to direct clean-up operations and to be responsible for the general sanitary conditions of the plant and surroundings. Of vital importance in this connection was the general condition that, unless trained, persons do not see what is happening beyond the point of the actual happening and do not realize the consequences of that happening.

To meet the need for trained personnel, at the request of the National Canners Association, a special training course in sanitation was given at the University of California at Berkeley from October 22 to December 15, 1945, with 23 persons from the industry in attendance. The course was designed to train the students in the theoretical and practical aspects of plant sanitation in order that they should understand the fundamentals of a sanitation program, and be able to evaluate methods and to cope with future developments in the rapidly expanding field of environmental sanitation. The course included discussions concerning how to secure cooperation of plant managers, plant employees, and official inspection personnel. Lectures, seminars, laboratory practice, and field exercises were given in four groups of courses, as follows:

I. Sanitary Science and Sanitary Inspection;
II. Plant Sanitation—Organization and Administration;
III. Public Health Aspects of the Plant Sanitation Program; and
IV. Laboratory Practices Relating to Plant Sanitation.

Sanitation Manual

During the eight-week training course, a Sanitation Manual for Food Industries was drafted as a class project.[2] In the foreword to

[2] *"Preliminary Draft of a Sanitation Manual for Food Industries,"* University of California Press (1946).

this publication, Mr. Walter S. Mangold, Associate Professor of Public Health, University of California, who designed and organized the eight-week course, outlines the evolution of the text as follows:

"Because of the shortness of time and the heavy daily schedule, it was foreseen that only an elementary approach could be expected. However, it proved to be an excellent class exercise, obliging the students to digest the fundamentals of sanitation and to apply them in a practical manner.

"The need of a Manual was discussed in class and a committee was elected to work over the chapter outlines and subheadings. The proposed outline was again discussed; then two students were assigned to the preparation and presentation of each chapter. An essay form of presentation was preferred, but certain groups believed that their subjects could be presented best in outline, and this was permitted. During the final week, the progress of the Manual stimulated much discussion, which resulted in numerous revisions before the papers were finally submitted.

"It is hoped that this limited class project will instigate further study and result in the drafting of a finished Manual."

The interest in the Manual indicated the value of making it available to the Industry, and therefore, the National Canners Association underwrote the printing of 3000 copies. They were all sold within six weeks, and an additional 600 copies within six months. Sections of this Manual have also been reprinted in *The Canning Trade* (1946).[3]

Association of Sanitarians

The 23 men who completed the eight-week training course form a nucleus of trained and experienced food plant sanitarians, and in their hands has been placed the responsibility by their employers for sanitary control of the food processing plants in which they are employed. It is worthy of note that the men who finished this course received a sanitarian's philosophy concerning sanitation, a foundation on which to develop their own thinking and a wholesome respect for the importance of their job.

At a meeting in November 1946, the men went on record as desiring to form themselves into a non-profit professional association of food industry sanitarians for the purpose of maintaining and improving the high sanitation standard in the canning, freezing, dehydrating and other food processing industries throughout the United States and its Territories. At the meeting held in May 1947, the group adopted a constitution, forming themselves into an organization known as "The Association

[3] 69 *The Canning Trade* (August 12, 1946) 7-8, 20-22.

of Food Industry Sanitarians." At this meeting there was considerable discussion by the group of revising the preliminary manual, and a publication committee was appointed. During November 1947, the group met again and prepared an outline of material to be used by various members of the group in drafting a revision of the manual.

1946 Educational Program

During 1946, the main emphasis was on a broad educational basis, but, where canners requested it, individual surveys were made. The educational program was directed mainly toward permanent, long term improvement in the industry, by creating a consciousness and a desire for better plant sanitation. In the spring of 1946, National Canners Association Sanitation Circular No. 2, entitled "A Guide to Plant Sanitation," [4] was prepared and distributed. This publication provided a brief resume and review of the general plant problems in a form that is easily read and understood by the usual plant operating personnel.

Beginning in the spring of 1946, two-day conferences were inaugurated by the National Canners Association staff throughout the country, in order that the operating personnel in canneries might be given specific and practical information on sanitation. The conferences were organized to appeal, in addition to managements and to superintendents, to foremen, foreladies, mechanics, engineers, etc., that is, to the people who actually do the work or supervise it. The success of these conferences indicated that the plant personnel are anxious for information concerning their responsibilities, and these conferences, in many cases, gave them a better concept regarding the importance and dignity of their position in the cannery than that heretofore understood.

To further the educational services, a two-week concentrated course in plant sanitation for members of the industry responsible for plant sanitation programs was held in December, 1946. The course was conducted by the National Canners Association staff and guest lecturers. It covered the fundamentals of sanitation that are pertinent to the food industry, with special reference to general industry problems as indicated from the sanitary surveys.

The basic principles involved in environmental sanitation were discussed during the course. Instruction included a study of the funda-

[4] National Canners Association, Washington, D. C. (May 1946).

mental principles of sanitary science as applied to specific problems arising from plant operation. It also included the evaluation and application of practical scientific measures for the correction of plant sanitation problems relating to water, sewage, industrial waste disposal, food, insects, rodents, ventilation, plumbing, plant construction, plant equipment, the improvement of plant lighting, the standards of sanitary facilities, and the practical application of those factors involved in industrial hygiene and communicable diseases which contribute to economic losses in the plant.

The technics of making a sanitary survey and of evaluating the data were described, and an opportunity was given for practical work. Those in attendance became acquainted with Federal, state and local legislation concerning sanitation standards, and the organization of inspectional services. The course was repeated in February and March 1947, and in all, 87 received certificates of attendance.

1947 Conferences

During the spring of 1947, two-day sanitation conferences were again held throughout the country, in cooperation with various state canners' associations. These meetings were similar to those held in 1946, had the same purpose, and the instruction was designed to further inform the same type of canning personnel concerning various phases of plant sanitation. The subject matter was altered somewhat and greater use was made of visual aid material.

On November 11, 12 and 13, 1947, the National Canners Association held a conference in San Francisco of plant sanitarians, for the purpose of exchanging information and experiences, discussing problems of mutual interest, and bringing the sanitarians up-to-date with recent developments and results of research on special projects. Over 100 persons attended. A great deal of valuable and practical information was obtained from the round table discussions.

Qualifications for Plant Sanitarians

As the program progresses and develops, it is becoming more and more evident that the details of sanitation are too many and the scope too wide for it to be successfully handled by anyone who can give it only passing attention. The management, and other top production men, have

little time to devote to it and shouldn't be required to give it their detailed attention. They should have for this work the assistance of some one with a specialized interest in sanitation. The job is more than mere janitorial work and housekeeping.

In the selection of a person to be trained for the job of plant sanitarian, certain qualifications have to be considered. He must be practical and have sufficient education to be able to apply technical information to everyday living. He must be tactful and able to accomplish his objective with the assistance of his fellow-workers. He must be able to become familiar with sanitation practices and details and understand the principles involved. He should be able to recognize quickly the existence of an insanitary condition and determine a course of action to cope with it. In addition to being able to correct or improve existing deficiencies, he should be able to conduct studies to develop improvements on unsatisfactory or inadequate procedures and new approaches to the solution of old problems. He should be able to apply his knowledge of sanitation to the alteration and repair of existing equipment, as well as to the development of new. There may be better and more economical ways of doing the job than those now in use. He should be an "on-the-job" instructor and supervisor, and therefore, be able to pass on information to his fellow-workers. He should be permitted to work with men of similar interests in order to receive the stimulation of such contacts and to maintain his own.

Practical Improvements

Experience has already demonstrated that trained personnel have done an excellent job in "raising the sights" of the industry and bringing about many practical improvements. Many problems are as yet unsolved, and the solution will have to come through studies made by the sanitarians working in the canneries and by research workers in the laboratories connected with the industry. Several research projects are in progress, and already practical results have been obtained on cleaning procedures and materials, chlorination of total plant water supply, lighting, and other sanitation problems.

Problems of Cleaning Programs

The task of cleaning is very difficult because in organizing a cleaning program one is often confronted with many problems such as time,

cost, and compatibility with production schedules, complex machinery and arrangement of equipment to be cleaned. Time is an extremely important item in many instances because during a packing season production pressure often reduces considerably the time alloted to cleaning.

The first requisite in planning a cleaning program is the selection of a crew under the direction of a competent foreman, whose interests are divorced from production, and whose main responsibility is the cleanliness of the plant. The crew should be a permanent part of the cannery organization, and they should be well trained in the procedures for using special cleaning tools, methods of dismantling equipment and in the significance of contamination and the hazards involved.

Criteria of cleanliness should be established, and it is suggested that equipment and canning areas be grouped according to the amount of cleaning necessary, such as:

(1) Areas needing constant attention;
(2) Areas needing attention every four to five hours;
(3) Areas needing attention every eight to ten hours;
(4) Areas needing attention daily;
(5) Areas needing attention weekly; and
(6) Areas needing attention annually.

Cleaning should be a year-round program in order that employees are always conscious of sanitation, and it should fit into a long-time planning program of changes in equipment design and new construction. An article discussing recent cleaning studies has been prepared by I. I. Somers, of the National Canners Association's Western Branch Laboratories, for publication early in 1948 in *Food Industries*.

Recent developments on "In-Plant Chlorination," which provides for a continuous application of chlorine water to equipment surfaces, have met with considerable success as a means of improving the general plant sanitation by reducing slime formation, eliminating odors, and shortening the shutdown time needed for clean up.

Studies on Lighting

The need for a study of plant lighting from the standpoint of performing specific seeing tasks, as well as for improving the overall plant lighting as an aid to better plant housekeeping and general plant sanita-

tion, was referred to in the discussion of conditions revealed by the individual plant surveys. In order to obtain basic information, the Association set up a research fellowship at Stanford University under the direction of Professor Leland H. Brown, Director of the Stanford University Illumination Laboratory, and David C. White was appointed research fellow to make studies on cannery lighting. This work is now in its second year, and the progress that has already been made is gratifying.

Disposal and Utilization of Waste

Concerning the problem of disposal and utilization of cannery waste, the Association, for many years, has been investigating existing methods and following the course of new developments in that field. It has also conducted collaborative studies with various agencies to obtain information applicable to cannery waste disposal problems. During this year, such studies have been carried on by N. H. Sanborn of the Washington laboratory, in cooperation with the Indiana State Board of Health, the Texas State Board of Health, and the Wisconsin State Board of Health. A review of the subject was presented by Mr. Sanborn before the Seventh Annual Food Conference in Boston in June 1947.[5]

Machinery Sanitation

An address on "Design of Sanitary Canning Equipment" was given by Paul C. Wilbur of the Food Machinery Corporation at the 1947 National Canners Association Convention in Atlantic City last January. It was published in the National Canners Association Supplement to the Information Letter with the other technical papers presented at that Convention.[6] Discussing the general problem of designing machinery for ease of cleaning, the following statements by Mr. Wilbur are of particular interest:

"Up to the present time relatively little attention has been given by design engineers to the broad aspects of machinery sanitation. True, wherever possible, machines have been made demountable or accessible for cleaning on an 'end-of-the-shift' basis. Fillers particularly, and also some of the equipment for handling finished or semi-finished material have been designed so that cleaning at the end of the day is at least possible, and in some cases easy. However, too little attention has been given to the

[5] 1 *Food Technology* (1947) 214-221.
[6] National Canners Association Information Letter, Supplement No. 1200, p. 95 (January 31, 1947).

general problem of designing machinery so that it will accumulate a minimum amount of rubbish and infection.

"The problem of machine maintenance and design to insure high sanitary standards is of great magnitude. It will not be solved overnight or by a single factor in the food industries, but should be considered a field for cooperative effort by manufacturers, users and public agencies."

Check List of Items of Sanitary Significance

An article on "Essentials of Sanitation for Canning Plants" by N. H. Sanborn of the Washington Laboratory of the National Canners Association [7] was published in the April 21, 1947 issue of *The Canning Trade* in compliance with many requests for a check list covering items of sanitary significance. There are included 106 items, in all, under the following headings:

Premises	4
Buildings	12
Water Supply	6
Raw Products and Ingredients	5
Machinery and Equipment	18
Containers	4
Waste Disposal	7
Drinking Water	7
Lunch Rooms	3
Toilets	16
Lavatories	8
Rest Rooms	5
Lockers and Dressing Rooms	5
First Aid and Medical Service	2
Requirements Affecting Employees	4
	106

Conclusion

In conclusion, it should be emphasized that sanitation and production are not opposing programs; rather, that in the long run sanitation will aid production and return profits in many indirect ways. A good start has been made along educational lines towards promoting better sanitation.

[7] 69 *The Canning Trade* (April 21, 1947) 7-8, 21.

It has to be realized, however, that it is not the function of the National Canners Association to police its members' plants. The Association acts in an advisory capacity only.

The value of the activities of the National Canners Association laboratories in sanitation to date is reflected in the continued demand for training selected cannery personnel, the large number of requests for information currently received, the excellent attendance at the various sanitation meetings, and the many improvements which canners have already made. To assist its members as far as practicable in the establishment of an adequate, projected sanitation program for their plants, the Association plans to continue to offer special training courses for cannery personnel selected to supervise the overall sanitation programs, to provide consultation service on problems relating to the operation and organization of plant sanitation programs, to conduct research investigations in its own laboratories, and to collaborate with other agencies on research projects pertinent to plant sanitation problems.

[*The End*]

NOTICES OF JUDGMENT

The Federal Security Agency has issued the following Notices of Judgment under the Federal Food, Drug, and Cosmetic Act: Foods Nos. 9601-9800, 9801-10000, issued October 1947, 10001-10200, issued November 1947; Drugs and Devices Nos. 1951-2000, issued August 1947, 2001-2050, issued November 1947; and Cosmetics Nos. 131-146, issued September 1947.

Notes and Comment

Judicial, Administrative, and Legislative Developments

Proposed Federal Standard Food Package Act . . . On June 17, 1947, the Legislative Committee of the National Conference on Weights and Measures conducted a public hearing at Indianapolis, Indiana, for the purpose of securing the comments and suggestions of industry with respect to the standardization of food packages by Federal law. In announcing this hearing, the Committee stated:

"The National Conference on Weights and Measures has been interested in legislation of this kind for many years, and believes that enactment of such legislation should be brought about at the earliest possible date. The proposed Bill is modeled very closely after H. R. 6784, which was introduced into the second session of the 77th Congress on March 13, 1942, by Congressman Somers of New York. The Committee recognizes the importance and far-reaching effect of legislation bringing about food package standardization; therefore, it earnestly solicits constructive criticism from all those interested. To this end, may we hear from you at an early date advising your organization will be represented at the forthcoming hearing."

The hearing was conducted by Mr. Rollin E. Meek, Chairman of the Legislative Committee, with the assistance of Mr. Joseph Blickley, a member of the Committee. Various segments of the food industry were represented at the hearing, and the Grocery Manufacturers Association was represented by Mr. Frank T. Dierson, Assistant General Counsel. The opinion of those appearing at the hearing was unanimous in opposition to the proposal that the size of food packages be standardized by federal law. The fundamental ground for rejection advanced at the hearing was that the proposed legislation appeared to be unnecessary because the consuming public is adequately protected by existing Federal and state laws. It was pointed out that the suggestion that there was a need for this legislation was based on a false assumption. The implication of the proposal that the food manufacturing industry generally attempts to defraud the public by manipulation of package weights and sizes was shown to be contrary to the known facts. It was made clear that the food industry recognized its great public responsibility and that unless the industry lived up to this responsibility, it was just

wasting its large investment in consumer advertising. The suggestion that any responsible food manufacturers would risk loss of this investment by petty fraud was demonstrated to be unwarranted.

In addition, practical objections of expense, arising out of the scrapping of millions of dollars worth of packaging machinery, were related to the Committee. It was also pointed out that the consumers' needs and tastes definitely entered into the determination of the size at which various food commodities are sold and that such needs far outweighed any benefits which might be realized by consumers by requiring foods to be sold in specified sizes.

Under the circumstances, the Legislative Committee rendered a report to the National Conference on September 24, 1947, in which it pointed out that, without exception, the position of all of those who attended the hearing was either in opposition to the bill or requesting exemption from its provisions as it related to their particular industry. In view of the unanimity of the opposition, the Legislative Committee expressed the opinion that it seemed inadvisable to press for the enactment of the Federal Standard Food Package Act and summarized the objections to it as follows:

"1. The tremendous cost to industry, which cost would ultimately be passed on to the consumer, to change its food packaging machines so that various food items could be packed according to the standards proposed.

"2. Industry is geared for the manufacture of the sizes which are now being produced. Standardization, as proposed, would interfere with all-out production, encourage inflation, and would retard the foreign relief program.

"3. Various ready-to-eat breakfast foods, biscuits, crackers, etc., are being packaged in containers standardized by shape and volume rather than by weight. This permits the use of the same packaging materials, packaging machinery, and plants to package a variety of products. This would not be the case, due to the different densities and non-uniform weights of the foods mentioned, if required to be packed on a standard-weight basis.

"4. The impossibility of canning fruits, vegetables, meat products, sea foods, etc., having different specific gravities, on a net-content liquid-capacity basis without creating a multiplicity of slightly different can sizes or violating slack-fill provisions of existing law.

"5. Food package standardization would endanger such practices as packaging food items on the basis of servings; as ingredients for making certain amounts of finished products of approved quality and palatability; to sell for the "magic" five and ten cent prices; and in containers which often have some definite value to the purchaser."

The recommendation made by the Committee to the Conference was as follows:

"The Committee recommends that the proposed food package standardization bill be left in the hands of the Committee on Legislation for further study and that no action be taken to bring about its introduction into the Congress until greater public support is obtained and it can be redrafted in such a manner that it will prove to be more acceptable to industry than it is in its present form. In the meantime, the Conference should encourage and be of every assistance possible to those industries wishing to have standardization legislation enacted for their particular products, as has been the case—on a State level—with such foods as flour, milk, bread, eggs, etc. . . ."

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Five Articles of Drugs Condemned as Not Bearing "Adequate Directions for Use" . . . The United States filed a libel of information against five articles, all of which were alleged to be drugs. The District Court determined that all the articles seized were intended for use in the cure, mitigation, treatment or prevention of disease in man or intended to affect the structure or function of the body of man, and were therefore articles of drugs under the Food, Drug, and Cosmetic Act. The Court further found that the labeling on the articles did not bear "adequate directions for use" and condemned all five articles.

It appeared that the first article of drug was labeled in part "Bush Mulso Tablets" and contained the statement "Directions: 3 to 6 tablets after meals as required" and the further statement "Provides the absorbing properties of charcoal with the proteolytic enzymes of papain." The Court was of the opinion that these statements suggest that the article was intended for use in the diagnosis, cure, mitigation, treatment, or prevention of some disease in man, or to have an effect upon some structure or some function of the body of man, and that, standing without a further statement as to its intended use, it was misleading.

The second article was labeled in part "Sulpho" and contained the statement "For use by those who delight in sulphur baths" and the further statement "Concentrate of Sulphur Mineral Hot Springs Water consisting essentially of the Polysulphides and Sulphides of Calcium and Sodium." It also contained instructions about temperature of the bath water and a caution against allowing the article to get near the eyes or hair. These statements were also felt by the Court to indicate that the article was a drug and that the directions for use were inadequate.

The third article was labeled in part "Bush Endo-Veg." The labeling suggested that the Endo-Veg Tablets be taken with each meal

and further stated that "Six tablets will provide 0.84 mg. of iodine which is eight times the minimum daily adult and child's requirements." The label contained the further statement "As a dietary source of iodine." The Court concluded that these statements indicated that the article was a drug and that the labeling did not inform the consumer of the use of the said drug and were therefore not adequate directions for use.

The fourth article was labeled in part "Garlic-Parsley Tablets" and contained the statement "Each tablet contains 3 grains of dehydrated Garlic and 3 grains of dehydrated Parsley with sugar, vegetable gums and artificial color as tablet binders and coating" and further stated "Suggested Use: For those persons wishing to include garlic and parsley in the regular diet, two of these tablets taken three times a day offers a convenient easy method. (No evidence of physiologic or therapeutic value.)" The Court was of the opinion that these statements suggested that the article was a drug and that the statement "No evidence of physiologic or therapeutic value," which may have been intended by the shipper to avoid the effect of the Federal Food, Drug, and Cosmetic Act, only gave the consumer information that the said Garlic-Parsley Tablets have no use whatsoever rather than stating an intended use for them. Under the circumstances, this labeling was felt to be inadequate.

The fifth article was labeled in part "Bush Lemo Tabs" and contained the statement "A special dietary source of Vitamin C" and the further statement "Suggested Use—One to two tablets daily. . . . Each tablet provides the adult with the minimum daily requirements of Vitamin C and the child with 1½ times the minimum requirements." The Court felt that these statements indicated that the article was a drug and that the directions for use did not inform the consumer of any use of the said drug and were therefore inadequate directions for use. (*United States v. 150 packages, more or less, of an article of drug labeled in part "Bush Mulso Tablets"; 95 bottles, more or less, of an article of drug labeled in part "Sulpho"; 143 packages, more or less, of an article of drug labeled in part "Bush Endo-Veg"; 24 dozen packages, more or less, of an article of drug labeled in part "Garlic-Parsley Tablets"*; and *16 dozen packages, more or less, of an article of drug labeled in part "Bush Lemo Tabs."* In the District Court of the United States for the Eastern District of Missouri, Eastern Division. No. 4415. July 11, 1947. [*CCH Food Drug Cosmetic Law Reports* ¶ 7059.])

The Court in the foregoing proceeding reached the conclusion that all five of these articles were misbranded because they failed to include in the labeling a statement of the purpose for which the article was to be taken. The law and the regulations seem to require that adequate directions for use should contain not only the statement of the dosage, in those cases where such directions are required, but also a statement of the purpose for which the article is to be taken, naming the disease or the effect upon the structure or function of the body for which the article is to be taken. Directions for use are not adequate unless the purpose for which the drug is to be taken, as well as the amount to be taken, appear on the label. However, it seems that some argument could be made that the bottles of "Sulpho" and the packages of "Bush Lemo Tabs" are not drugs at all and that the labeling appearing thereon did not indicate that they were articles intended for use in the diagnosis, cure, etc., of disease in man. The sulphur baths might merely be taken for the purpose of relaxation rather than for any other purpose. With respect to the "Bush Lemo Tabs," it would seem that these might possibly be classed as special dietary foods rather than as drugs. While this case has decided these issues in favor of the position that these articles are drugs, it would seem likely that there will be further argument in the future with respect to the propriety of this determination.

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Goods Intended for Export Ordered To Be Released . . . Some cases of catsup were seized in a libel proceeding on the ground that they were adulterated because of a high mould count. It appeared, however, that the goods were still fit for human consumption and that they were intended for export, although not so labeled. The goods seized could never be brought into compliance with the Federal Food, Drug, and Cosmetic Act so far as domestic sale or use was concerned. However, as there appeared to be no question but that the goods were never intended for domestic sale and that the seizure could have been avoided merely by the use of a label indicating intention to export, the Court granted a motion directing the United States Marshal to release the goods to the owners so that they could sell such goods for export purposes only. The Court pointed out that there is a conflict of opinion with relation to the bearing of the export section of the statute upon the section requiring that domestic goods either be destroyed or brought

into compliance. The Court resolved this conflict in favor of permitting the export of the goods without bringing them into compliance but expressed the hope that the conflict would be settled by an authoritative decision of the Circuit Court of Appeals. (*United States v. 215 cases, more or less, each case containing 24 bottles of an article labeled in part: (bottles) "Michigan Brand Grade A Tomato Catsup Contents 14 Oz. Avoir. . . ." United States of America v. 902 cases, more or less, each case containing 24 bottles of an article labeled in part: (bottles) "Michigan Brand Grade A Tomato Catsup Contents 14 Oz. Avoir. . . ."* In the United States District Court for the Eastern District of New York. Misc. No. 1152. July 3, 1947. [*CCH Food Drug Cosmetic Law Reports* ¶ 7058.])

In granting the foregoing motion, the Court exercised a practical common-sense viewpoint. As this catsup was fit for human consumption and met the specifications of the foreign purchaser and was not in conflict with the laws of the country to which they were to be sent, the Court could not countenance this useless destruction of food when the entire matter could have been avoided if the goods were merely labeled to indicate that they were intended for export. Although the seizure was justified because the statute was not literally complied with, the equities of the situation required that the goods should be made available for use as food under the circumstances disclosed.

[On reargument October 22, 1947, the Court stated ". . . assuming, and even finding as a fact, that the claimants did not intend to export the goods, but planned to dispose of them in the domestic market, I still adhere to my original determination."]

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Supreme Court Proceedings of Interest . . . The Supreme Court has refused to review the case of *United States v. William Ray Olsen,* in which the United States Circuit Court of Appeals for the Ninth Circuit held that the government had the right, under Section 304 (a) of the Federal Food, Drug, and Cosmetic Act, to seize a misbranded machinery or apparatus from the home of a private person when it had been mislabeled at the time it had been shipped in interstate commerce.

On the other hand, certiorari has been granted by the United States Supreme Court in the case of *United States v. Jordan James Sullivan, trading as Sullivan's Pharmacy,* in which the Circuit Court for the Fifth Circuit held that a retail pharmacist is not subject to Section 301(k) of the Federal Food, Drug, and Cosmetic Act.

Both of these cases have been previously discussed in these Notes in previous issues [1 *Food Drug Cosmetic Law Quarterly* (1946) 604-606, 610, 611, 2 *Food Drug Cosmetic Law Quarterly* (1947) 276, 277, 462-466, 470].

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Regulations under the Federal Insecticide, Fungicide, and Rodenticide Act . . . The rules and regulations authorized by the Federal Insecticide, Fungicide, and Rodenticide Act have been issued by the Secretary of Agriculture and may be found in the *Federal Register* of October 2, 1947, 12 F. R. 6493. They became effective November 1, 1947. It is provided that registration of rodenticides and weed killers must be accomplished by December 25, 1947. Insecticides and fungicides, including disinfectants, must be registered by June 25, 1948. In view of the relatively short time in which applications may be made, the wholehearted cooperation of industry has been requested.

[The End]

"Notes and Comment" is a regular feature of the *Food Drug Cosmetic Law Quarterly,* written by Franklin M. Depew, who is of counsel for Standard Brands Incorporated.

Dr. Louis D. Elliott
A Biographical Vignette

Dr. Louis D. Elliott, Assistant Commissioner of Food and Drugs since December 1945, is responsible for law enforcement operations related to foods shipped in interstate commerce and is in charge of import control work.

Dr. Elliott was born in Ithaca, New York, in 1889, and spent his boyhood in California. He received his A. B. degree from Stanford University in 1911, and did graduate work at Cornell University from 1911 to 1913.

After entering Federal service in 1913 as a chemist at the New York Station of the Bureau of Chemistry, Dr. Elliott was at the San Francisco Station during 1917 and 1918. He was employed by the National Canners Association as a chemist in the Fish Inspection Service, San Pedro, California, from 1918 to 1922. Dr. Elliott received a Ph.D. degree from Stanford University in 1923, and during the same year re-entered the Bureau of Chemistry at the Seattle Station. He was Chief of the Denver Station from 1926 until he was transferred to Washington in 1929.

Dr. Elliott and his wife live at Falls Church, Virginia. They have three children and five grandchildren.

George P. Larrick
A Biographical Vignette

George P. Larrick, Assistant Commissioner of Food and Drugs since December 1945, is responsible for law enforcement operations relating to drugs and cosmetics, and has general charge of the inspection work of the field force, located in cities throughout the country.

Mr. Larrick was born in Springfield, Ohio, in 1901. He attended Wittenberg College and Ohio State University.

Entering the Federal service in 1923 as a Food and Drug Inspector at the Cincinnati Station, Mr. Larrick was transferred to the administrative offices of the Food and Drug Administration in Washington, in 1928. He became Chief Food and Drug Inspector in 1939, and in 1945, he was promoted to his present position.

Readers of the *Quarterly* will recall Mr. Larrick's penetrating and instructive analysis of "Sanitation Provisions of the Federal Food, Drug, and Cosmetic Act," appearing in the June 1946 issue of the *Quarterly*.

Mr. Larrick lives in Arlington, Virginia, with his wife, the former Miss Alice M. Gelsanliter. They have four children.

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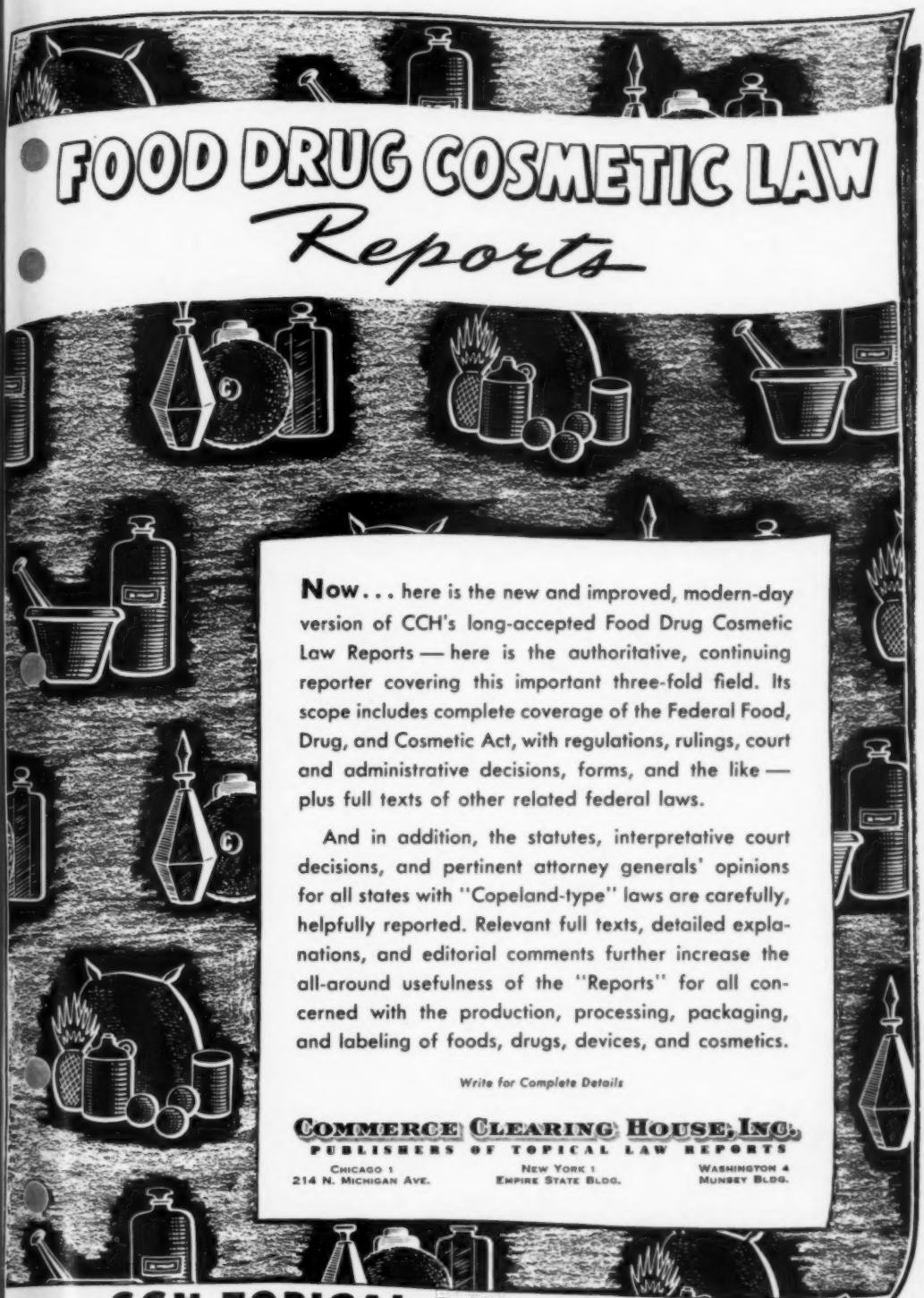

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